ICAT 2014
Vienna, Austria, 15. - 17. October 2014
International Conference on Additive Technologies

biomedical engineering

Additive Manufacturing, Verification and Implantation of Custom Titanium Implants

Radovan Hudák, Jozef Živčák,, Bruno Goban

Martin Lisý – Martin Gazárek – Lukáš Marinčák

ISO 13485 LL-C (Certification)

ISO 9001 LL-C (Certification)

Organization details

Company was established on 2010 as spin-off company of Technical University of Košice (TUKE) and CEIT a.s. holding (Central European Institute of Technology).

Company employes 7 employees, biomedical and material engineers who were direct students of TUKE, Faculty of mechanical engineering, Department of biomedical engineering and measurement.

free form modelling & development of prototypes

manufacturing of certified medical products, custom-made & in series

research & development of medical products

Organization details

custom implants made of titanium alloy (Ti-6Al-4V) (Grade 5) manufactured by the 3D printing technology
plastic and metal prototypes manufactured by the 3D printing technology, manufacture of anatomic models
3D scanning, digitalisation and modelling of medical products
medical data processing and adjustment
verification and validation of medical products
medical metrology and diagnostics
science and research in the field of implantology, implant manufacturing and medical sensorics

- Company is acredited producer of CMF custom-made implants: SIDC code – SK-13-0224
- Approved medical devices:
  - Custom-made cranial implant P91710
  - Custom-made maxillo-facial implant P91709
  - Custom-made cranio-maxillo-facial implant P91708

Organization details

Technical University of Kosice, Kosice, Slovakia

Louis Pasteur University Hospital, Kosice

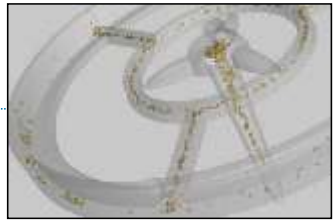
University of Veterinary Medicine and Pharmacy in Kosice, Slovakia

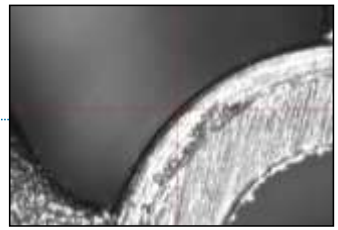
Pavol Jozef Safarik University in Kosice, Slovakia

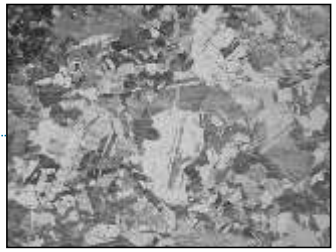
Kosice, Slovakia

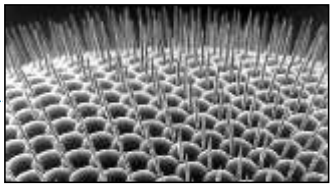
Technology and equipment

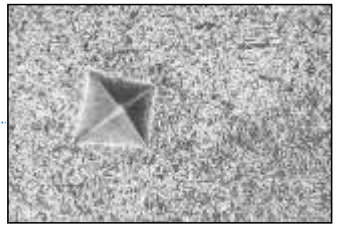
- industrial tomography
- geometric metrology
- metalography
- spectroscopy
- electron microscopy
- rougness measurement
- hardnes measurement
- thermography





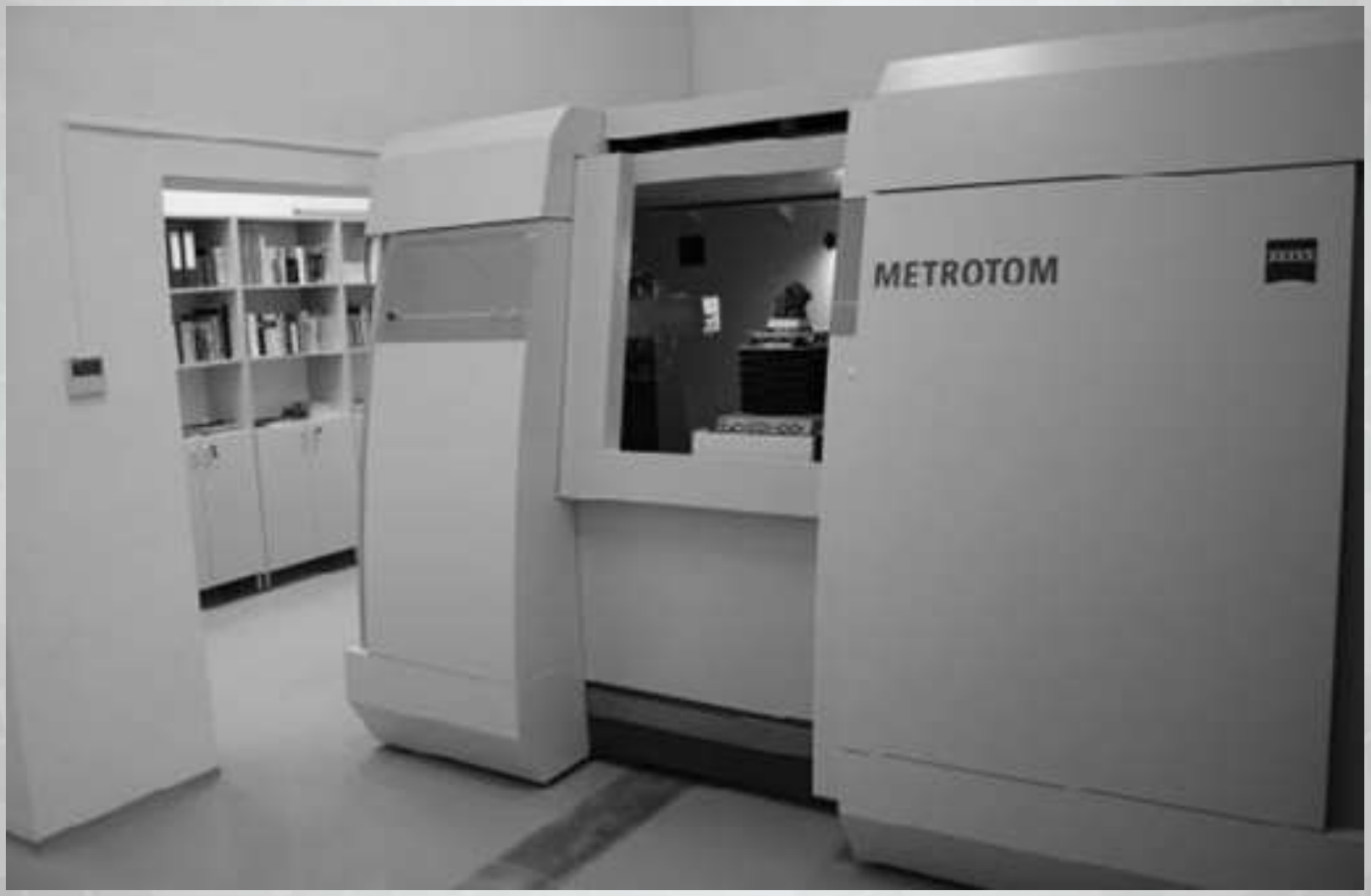






Technology and equipment

1. Metrotomography – ZEISS Metrotom 1500



Technology and equipment

1. Metrotomography – ZEISS Metrotom 1500

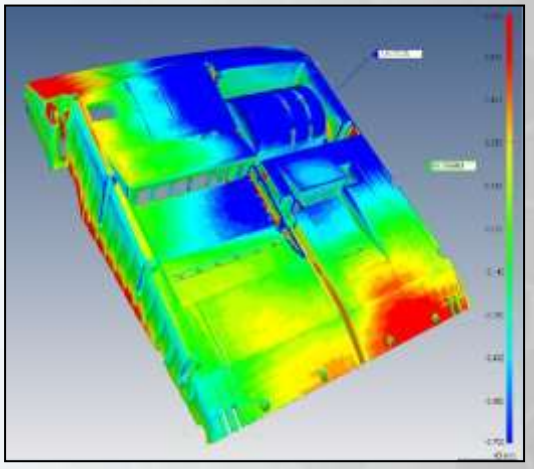
Technology and equipment

1. Metrotomography – ZEISS Metrotom 1500

X-ray → computer tomography → metrotomography

2D inspection

3D visualization
splines

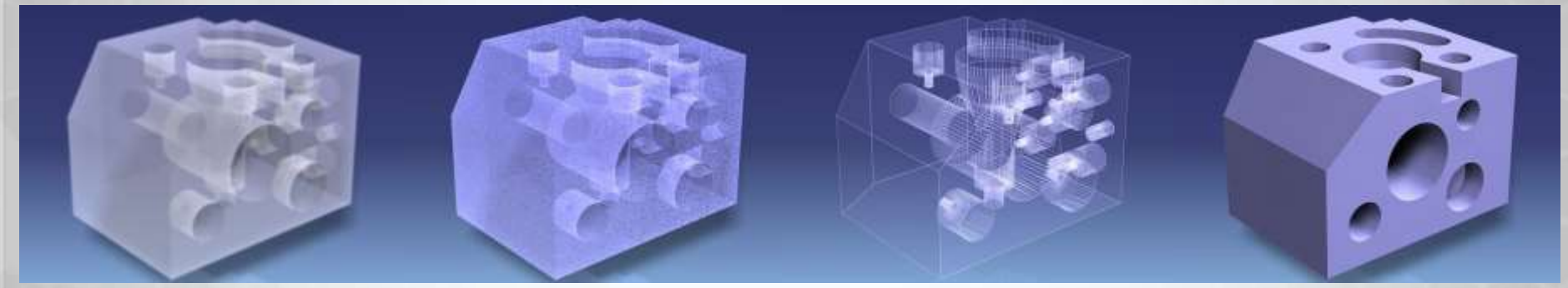


3D visualization
splines
measurements

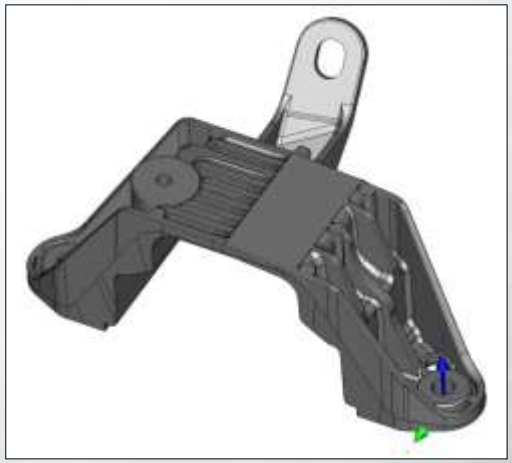
Technology and equipment

1. Metrotomography – ZEISS Metrotom 1500 (reverse engineering)

Volume model **Point cloud** **Splines** **CAD model**



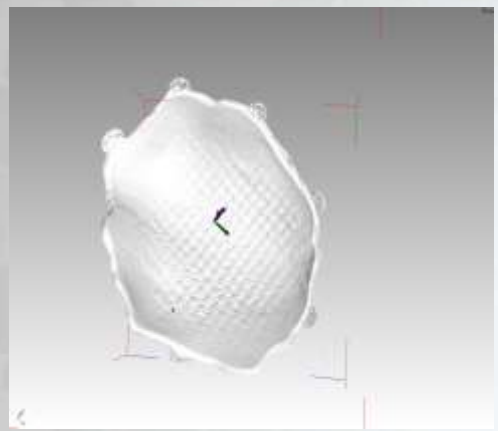
Real part

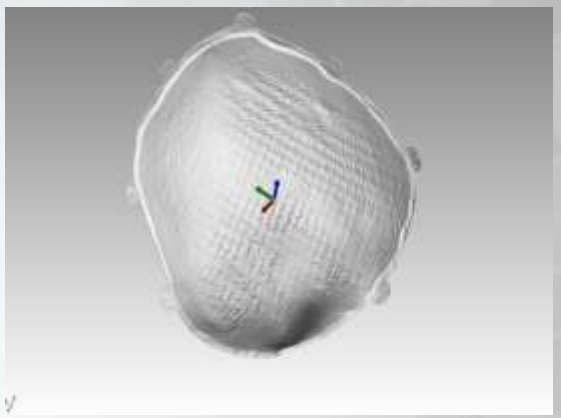


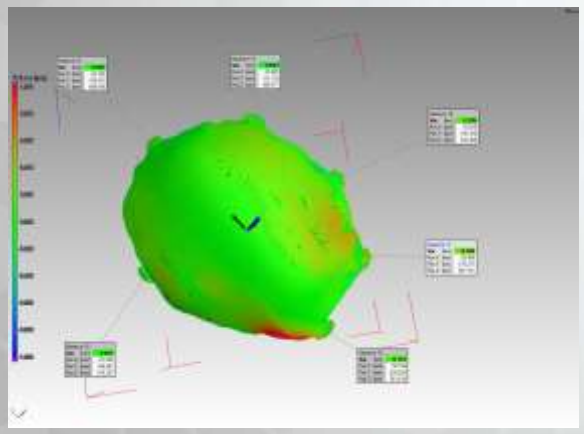
3D CAD model

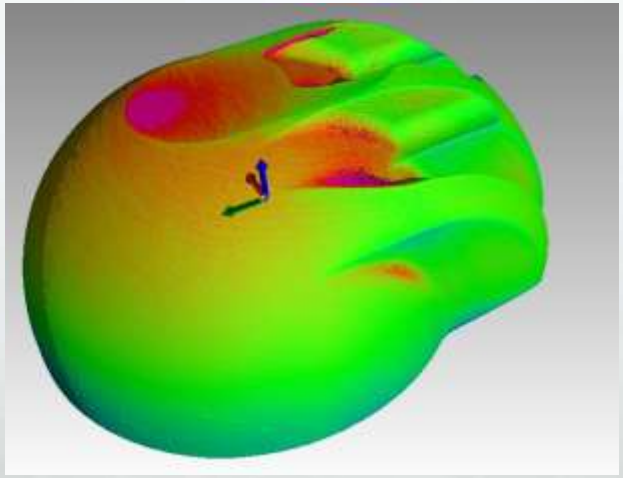
Technology and equipment

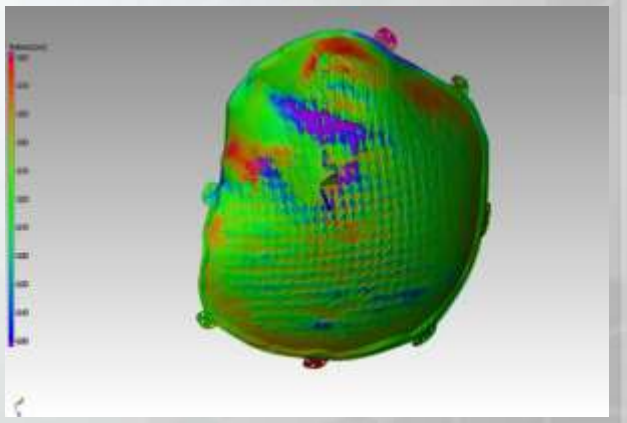
1. Metrotomography – ZEISS Metrotom 1500 (deviations)





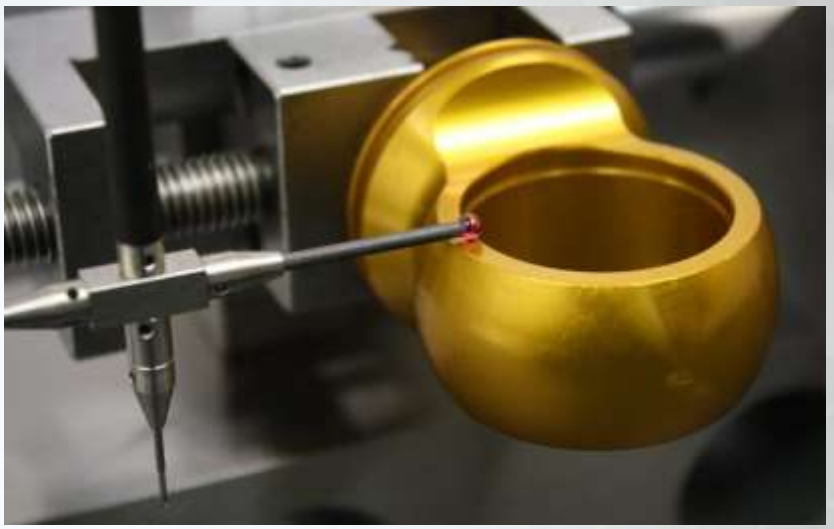






Technology and equipment

2. Coordinate metrology – ZEISS Contura G2



Technology and equipment

3. Scanning

Technology and equipment

4. Direct metal laser sintering lab – EOSINT M280

Building volume
(including building platform)
250 mm x 250 mm x 325 mm)

Laser type
Yb-fibre laser, 200 W

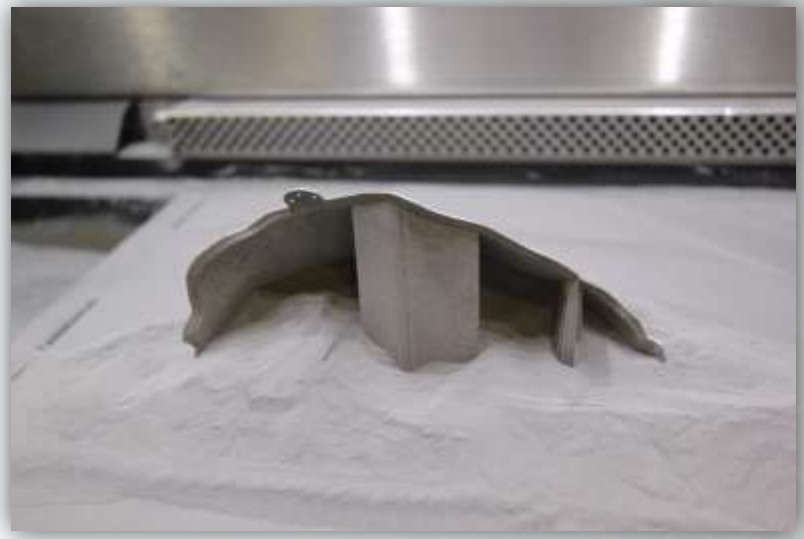
Precision optics
F-theta-lens, high-speed scanner

Scan speed
up to 7.0 m/s (23 ft./sec)

Variable focus diameter
100 - 500 µm (0.004 - 0.02 in)

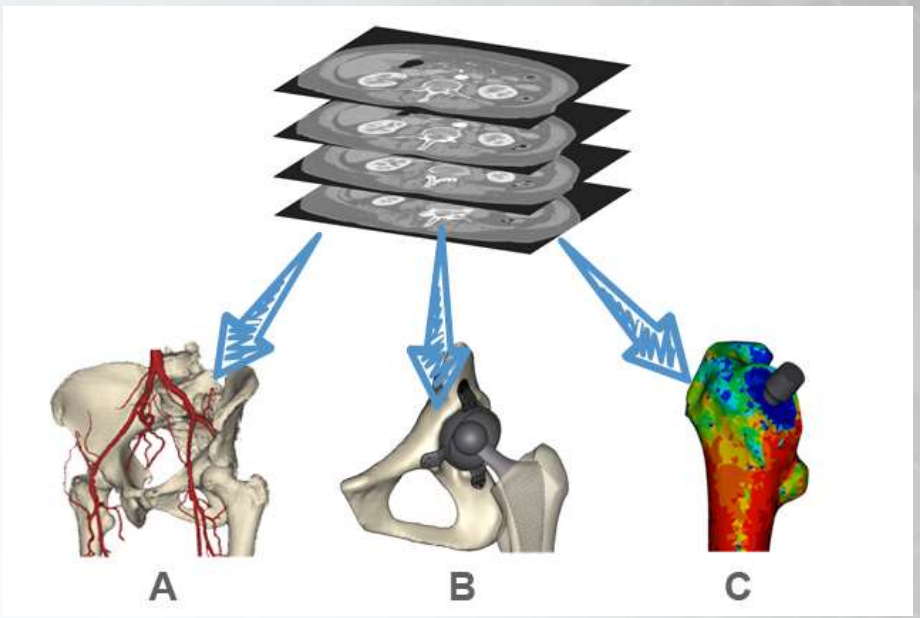
Technology and equipment

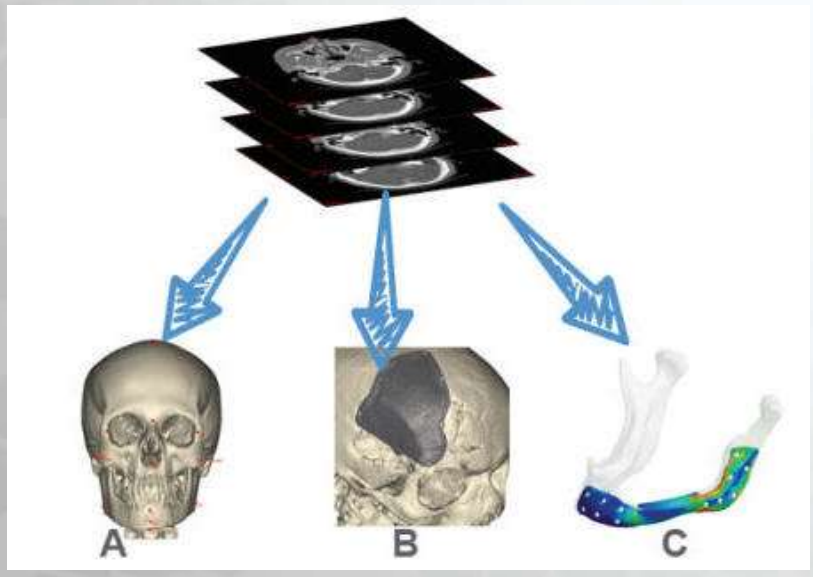
4. Direct metal laser sintering process – EOSINT M280

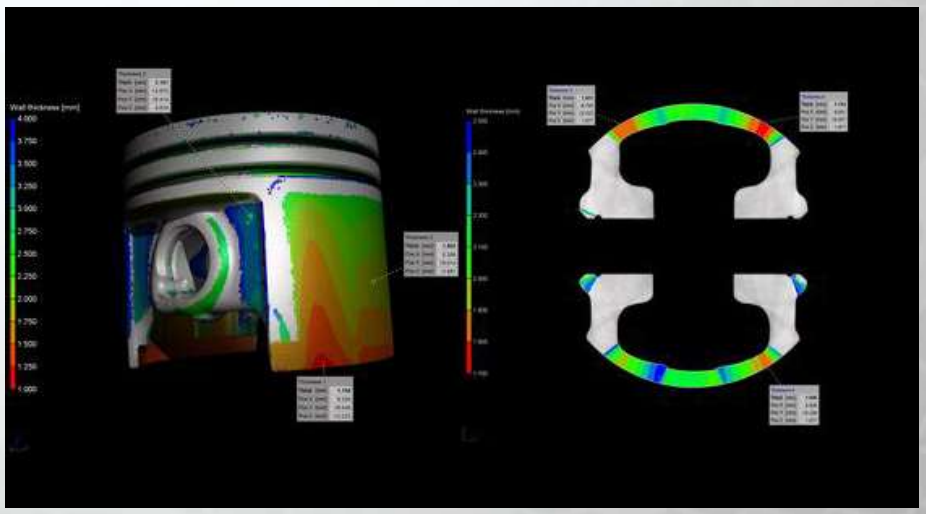


Technology and equipment - Software

1. Mimics - Materialise, Belgium
2. STL+ and 3Matic - Materialise, Belgium
3. Magics - Materialise, Belgium
4. Within Medical - Within, United Kingdom
5. Solidworks - Dassault Systèmes, USA
6. RapidForm - 3D Systems, USA
7. Geomagic - 3D Systems, USA
8. Calypso – ZEISS, Germany
9. VGStudio - Volume Graphics, Germany
10. Exocad – Exocad, Germany







CEIT biomedical engineering

*AM - a process of joining materials to make objects from 3D model data, usually layer upon layer (ASTM F2792 - 12a)

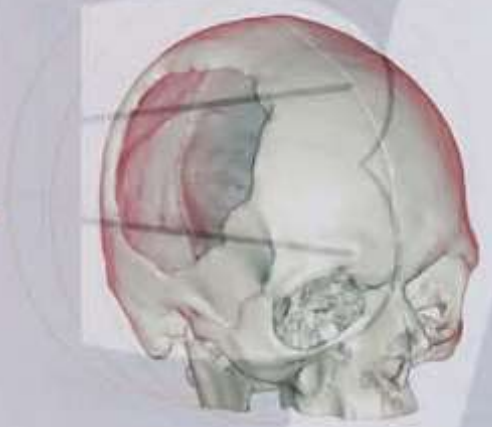
*AM/ step by step

process of development and manufacturing of a custom-made cranial implant applying the additive technology

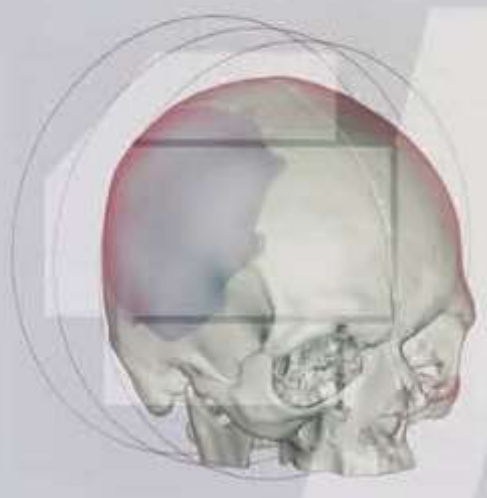
CEIT biomedical engineering

diagnostics

input data (CT, MRI)



referential model



implant modelling

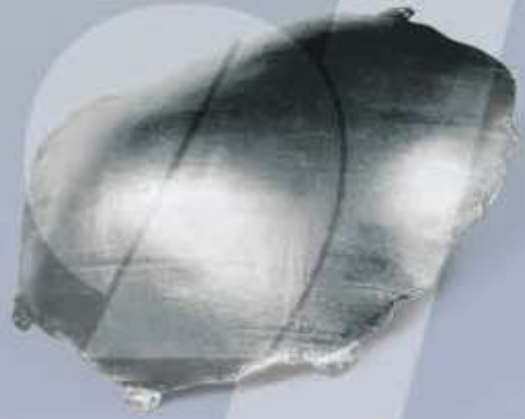
3D printing of prototypes

consulting

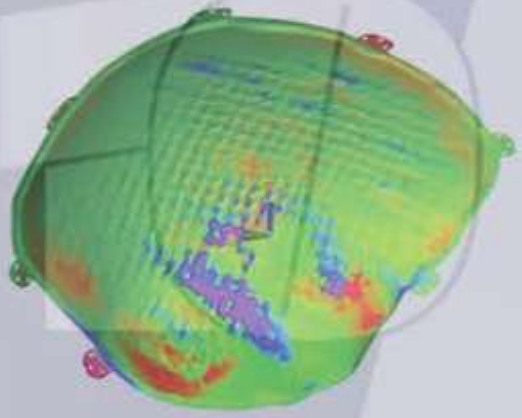
CEIT biomedical engineering

additive manufacture (AM)

postprocessing



implant Ti-Al6-V4 (Grade 5)



validation-metrotomography

surgery

after the reconstruction

Input data for AM

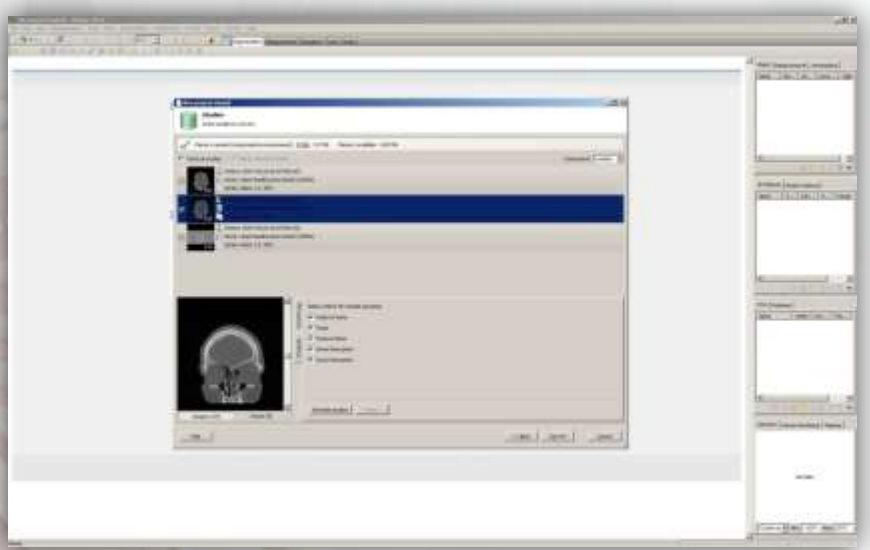
Body surface:
Optical and laser scanning, white and blue light scanning

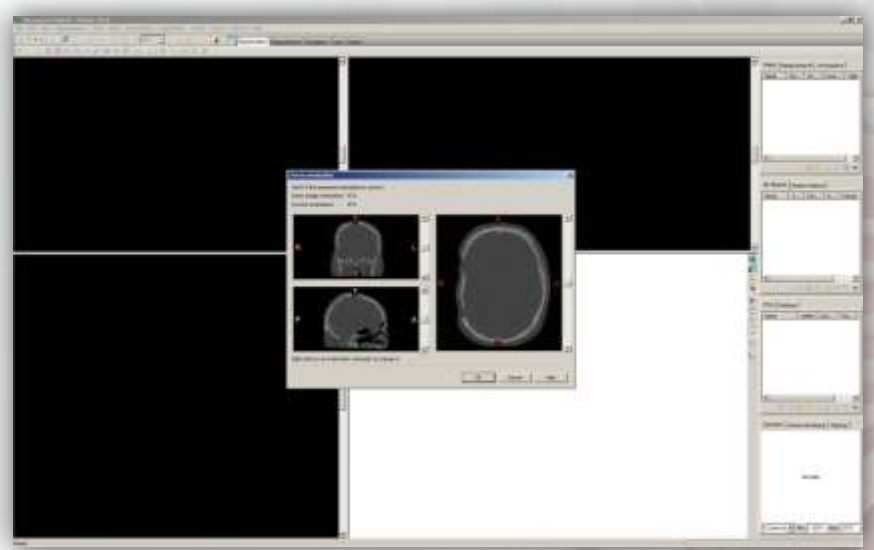
Bones:
CT/MRI/
DICOM data

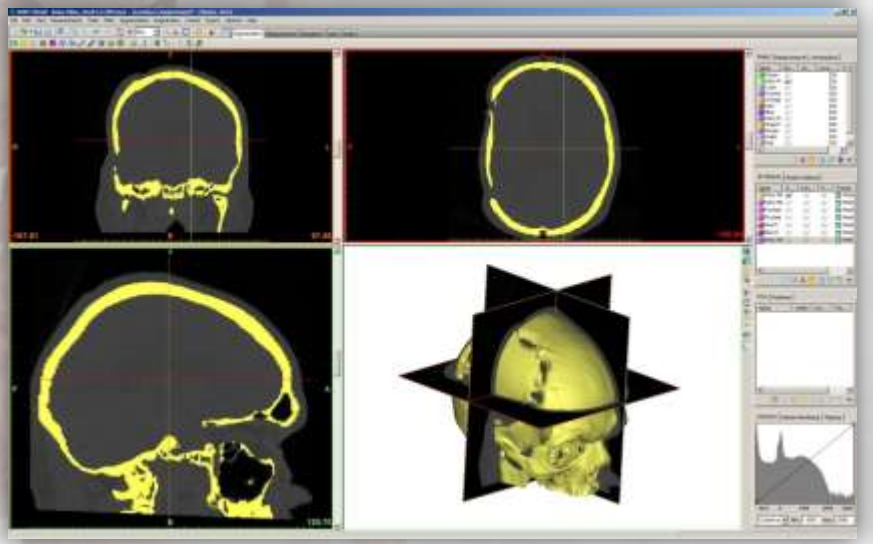
Inner organs:
CT/MRI/USG
DICOM data

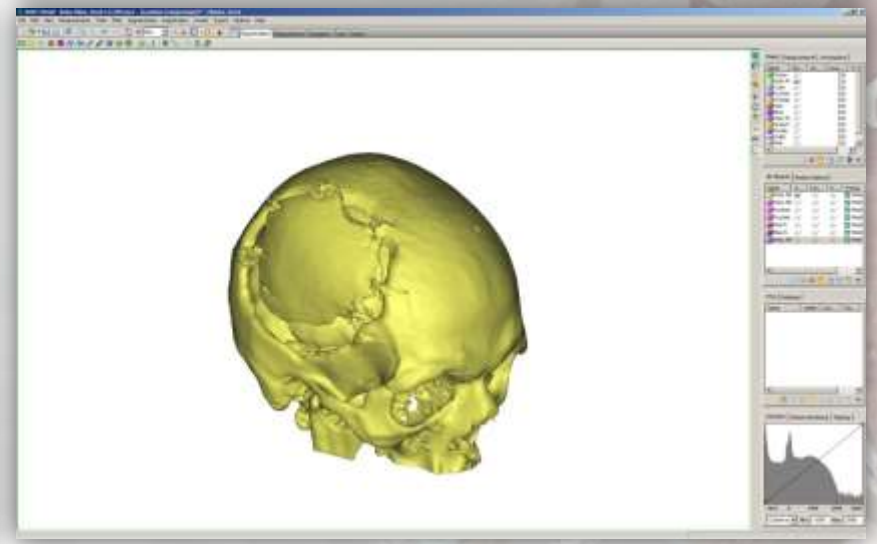
CASE STUDY 1 – Cranial implant

DICOM data transformation



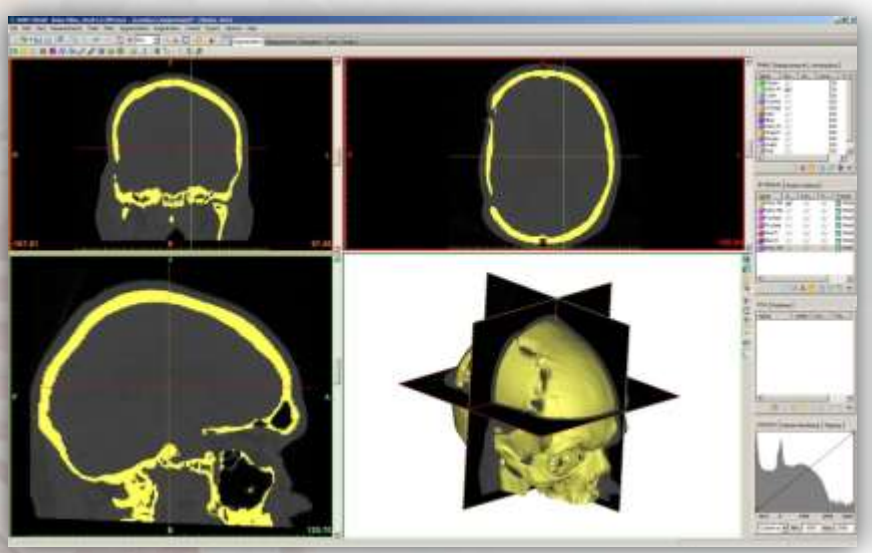


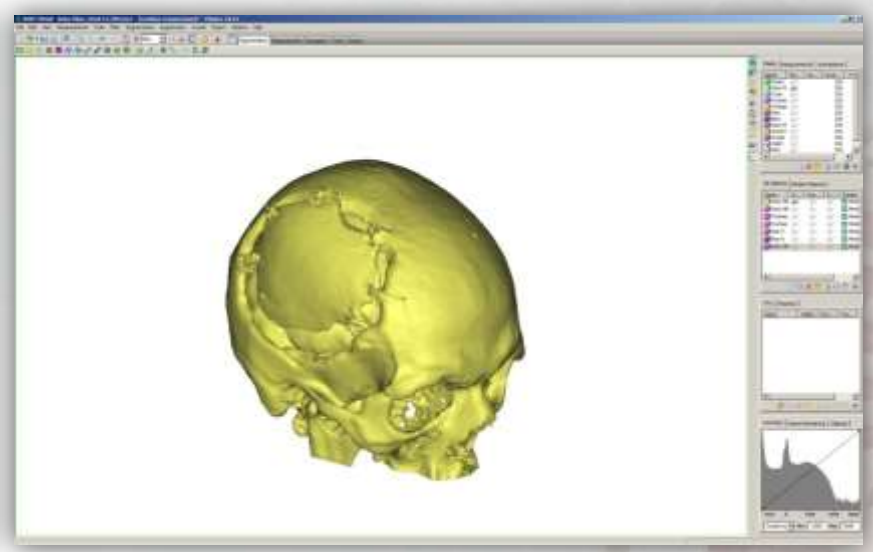


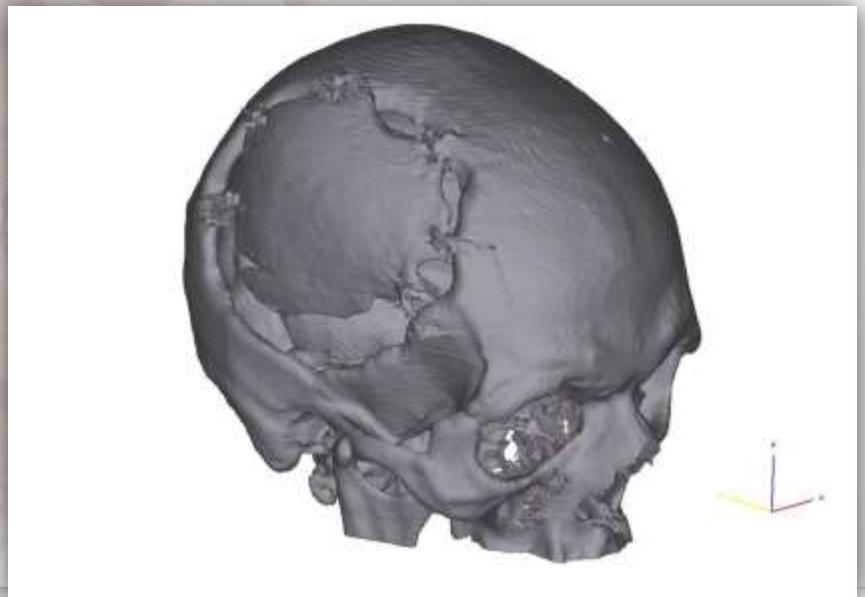


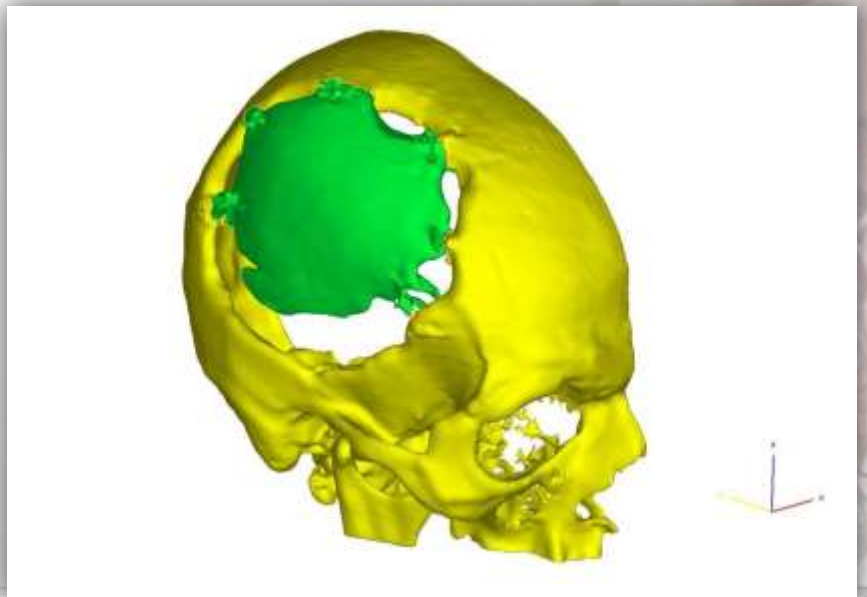
CASE STUDY 1 – Cranial implant

DICOM data transformation



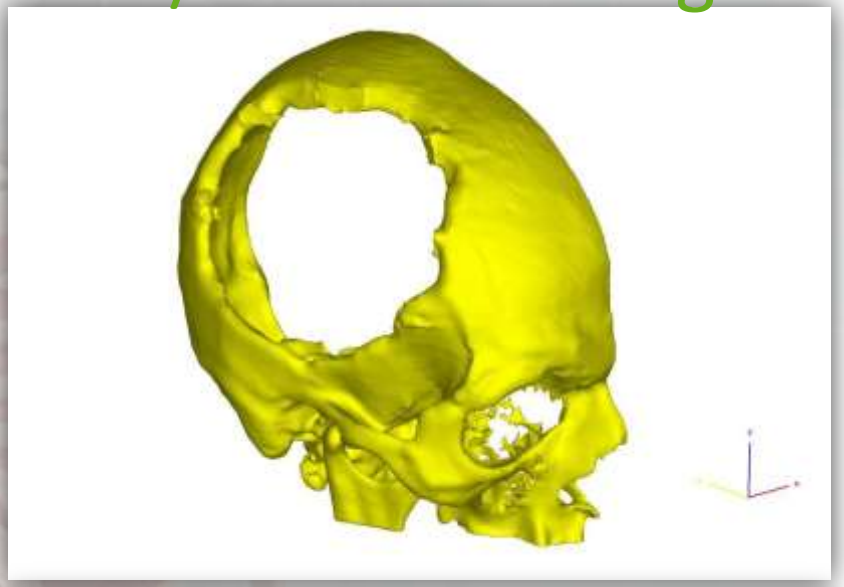


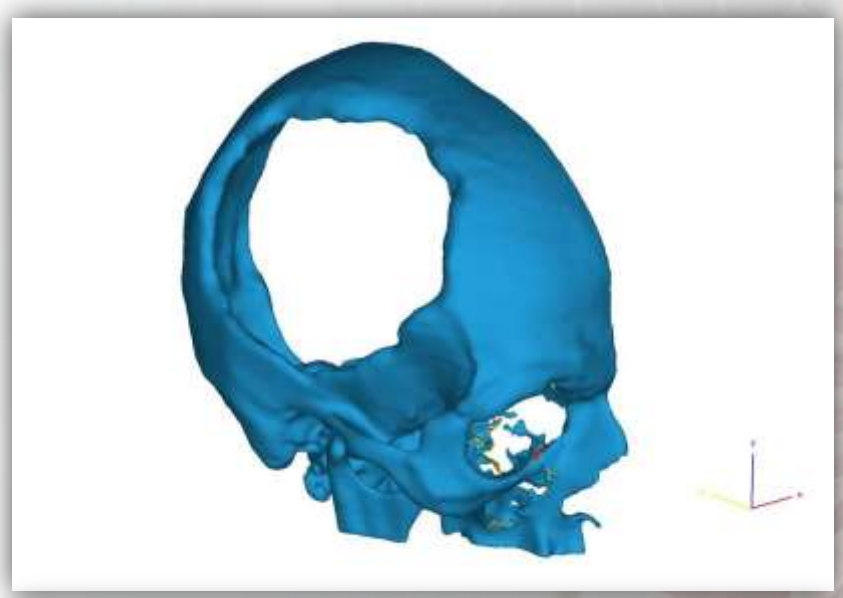


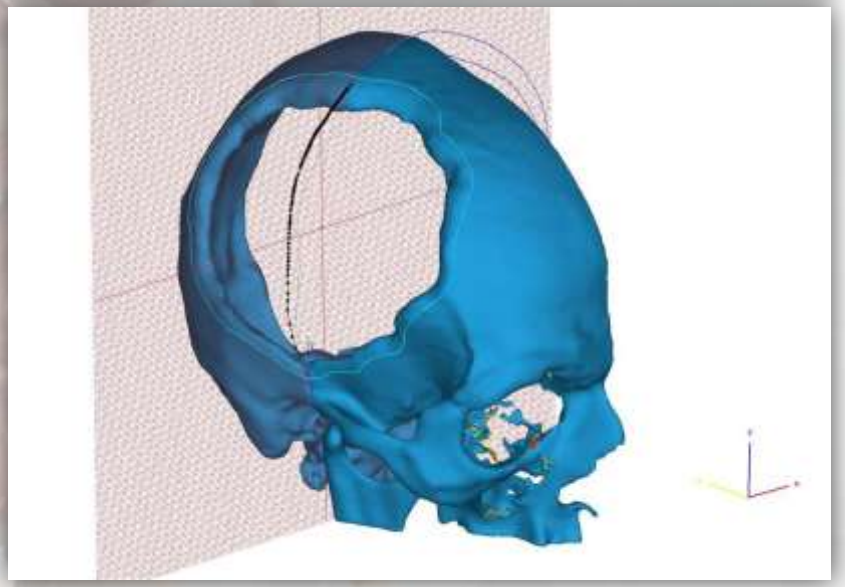


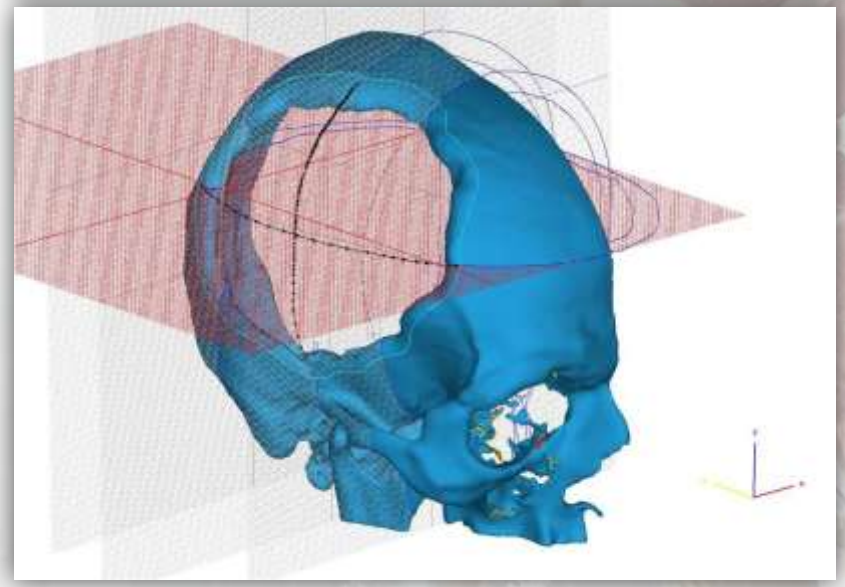
CASE STUDY 1 – Cranial implant

CAD/CAM modeling



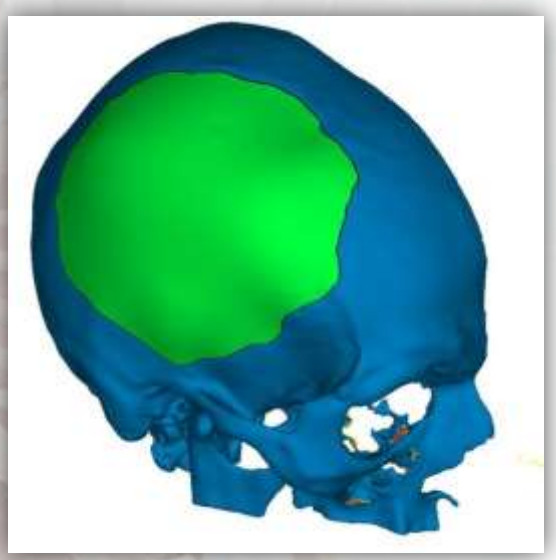


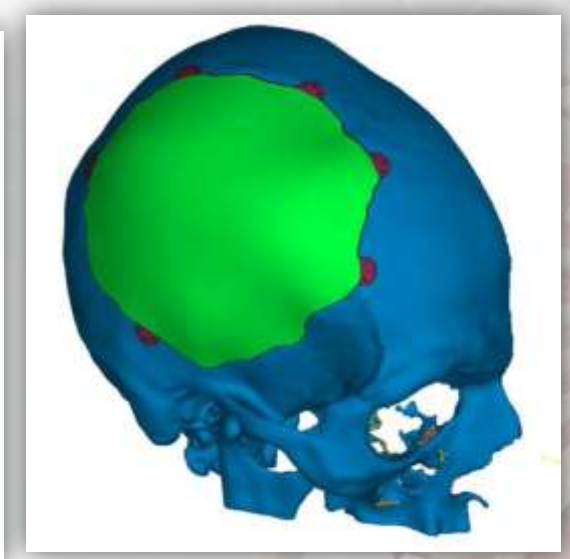


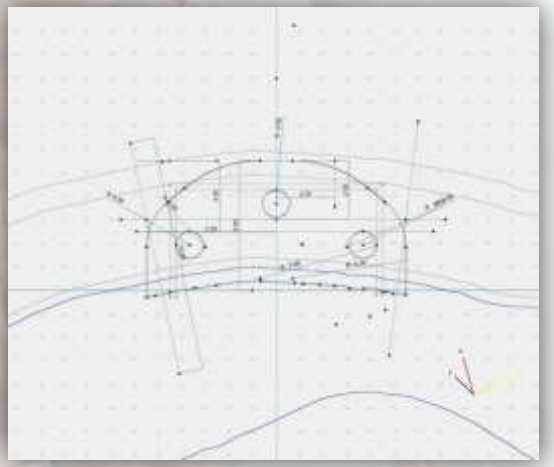


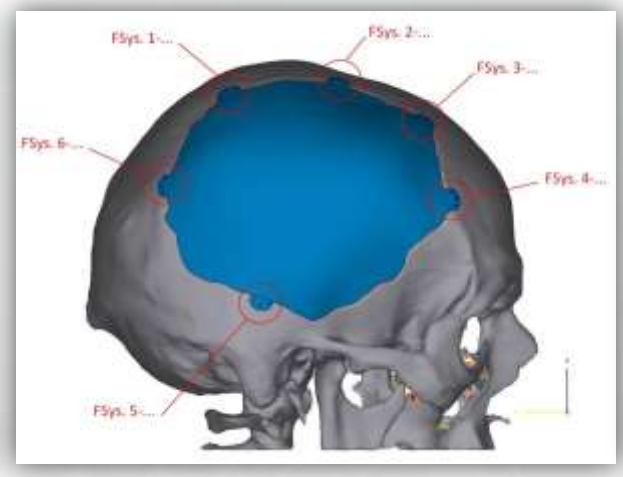
CASE STUDY 1 – Cranial implant

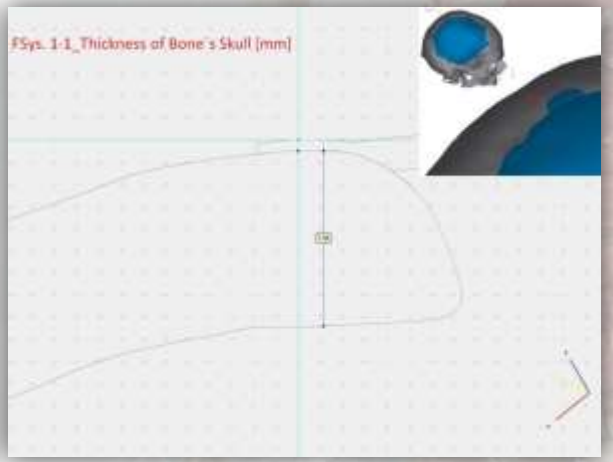
CAD/CAM modeling of fixation system











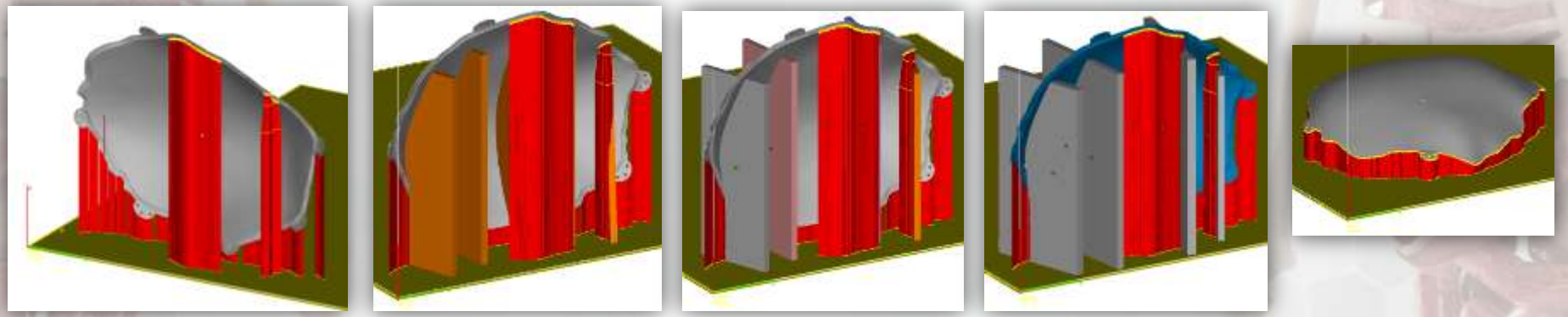
CASE STUDY 1 – Cranial implant

Production of cranial implant

Optimalization of production process

Cranial implant of requested parameters and dimensions based on input data (CT scan_DICOM data) , means custom-made for dedicated patient and based on specific study of surgeon, or specific medical application was realized by „V. version“ (position, support material , etc.).

I. Version *II. Version* *III. Version* *IV. Version* *V. Version*

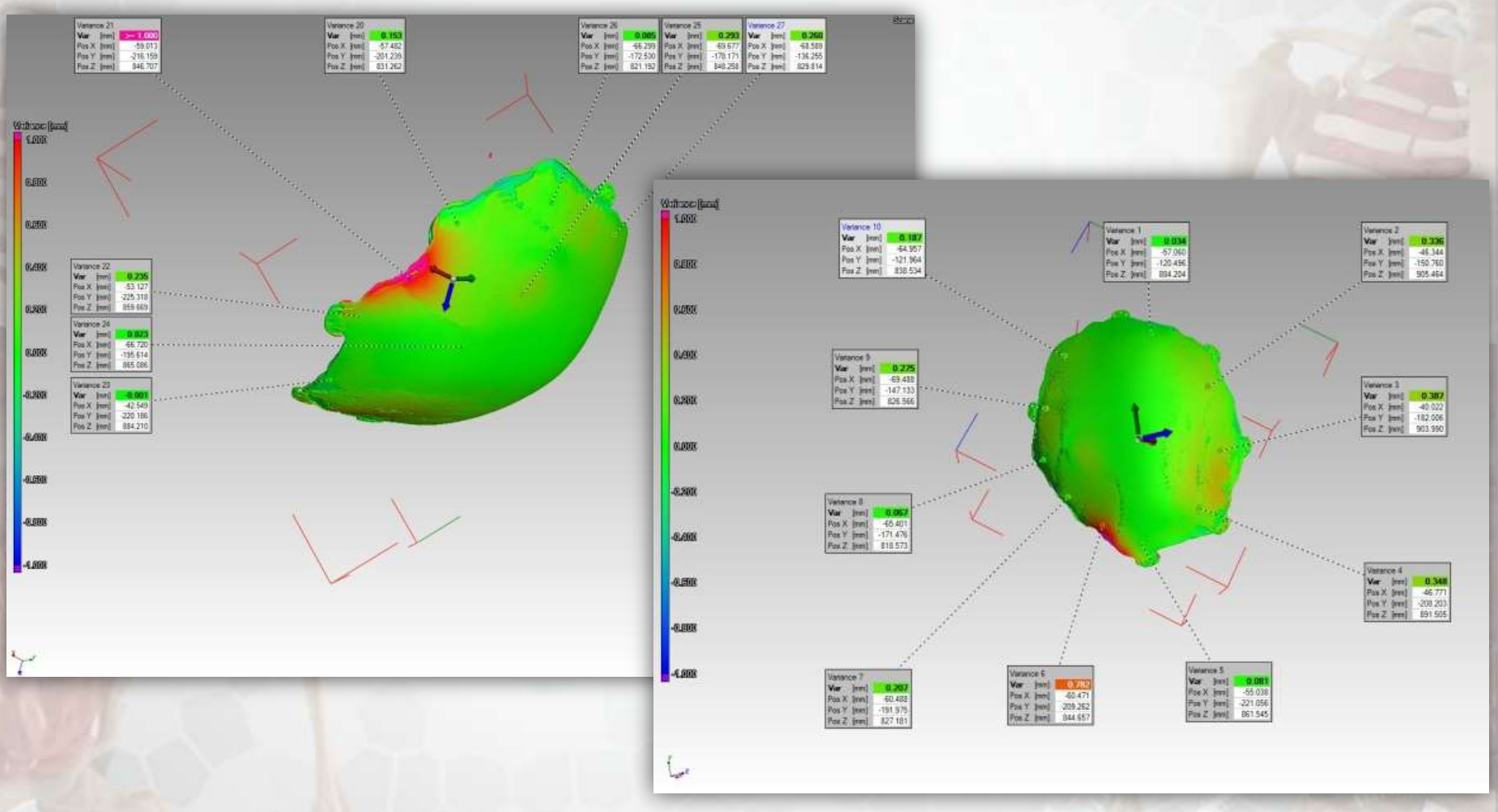


For each version the position of the part (cranial implant) was changed with specific change of support material and removed after heat treatment. Support/ Part Exposure Parameters“ were not changed, these parameters were identical for all versions.

CASE STUDY 1 – Cranial implant

Production of cranial implant

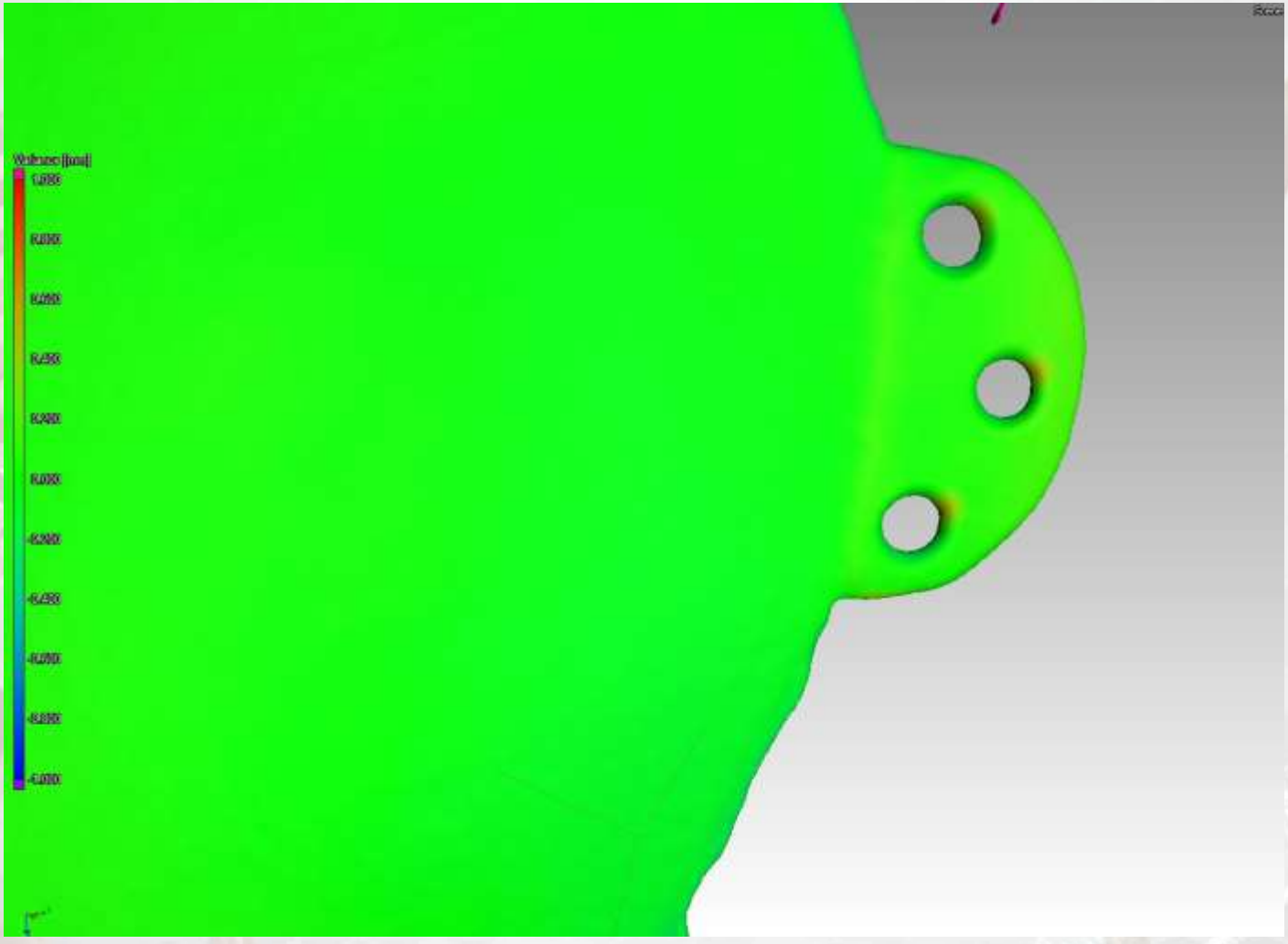
Shape and size validation by Computed Tomography



CASE STUDY 1 – Cranial implant

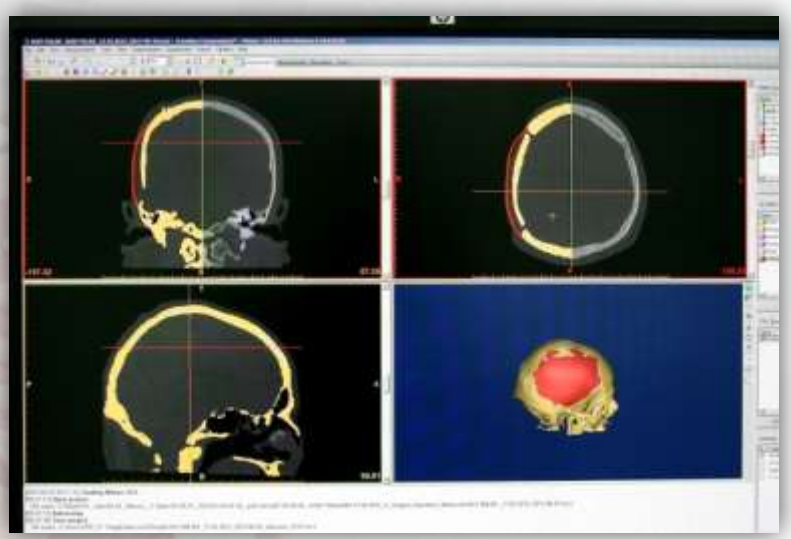
Production of cranial implant

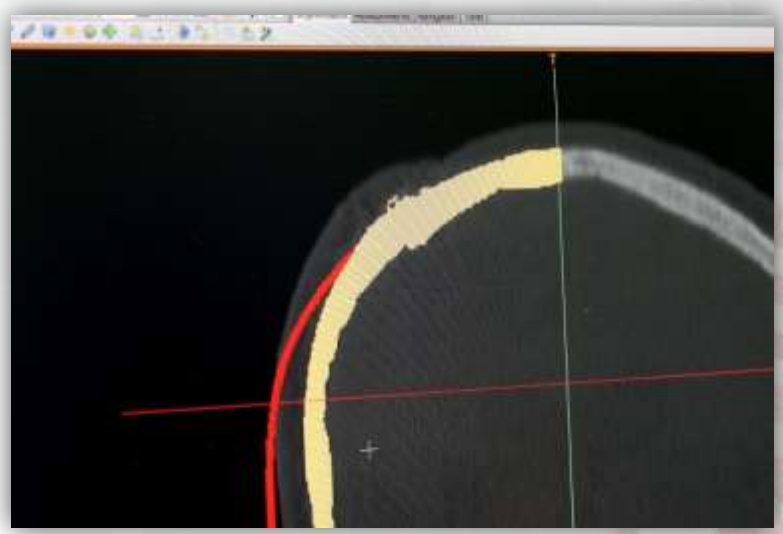
Shape and size validation by Computed Tomography

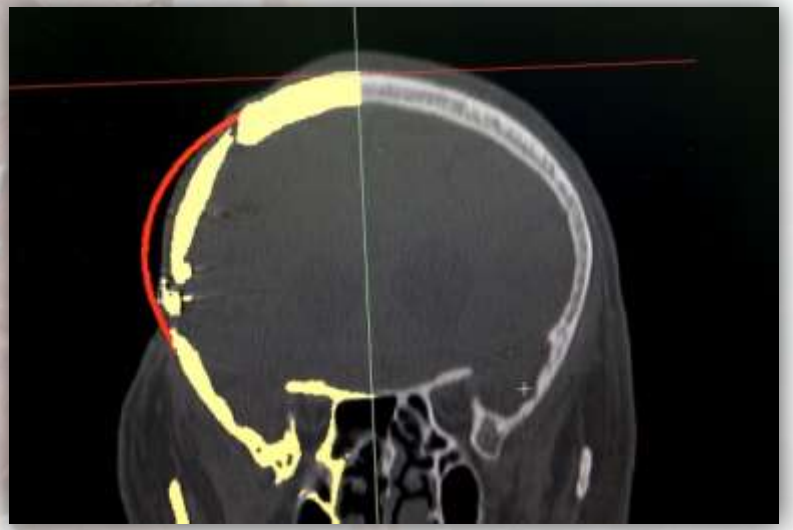


CASE STUDY 1 – Cranial implant

Planning of the surgery





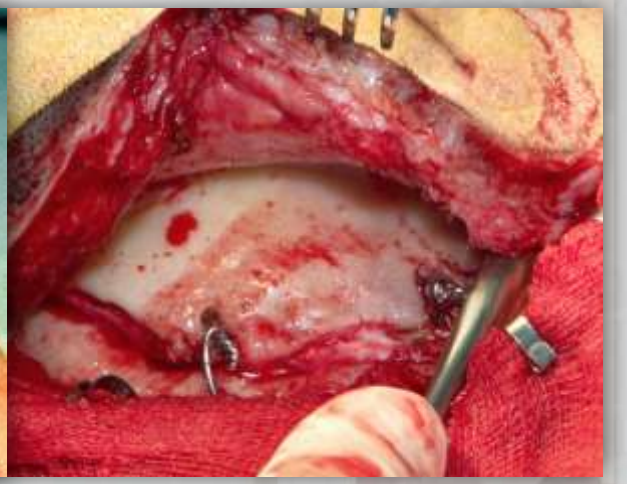


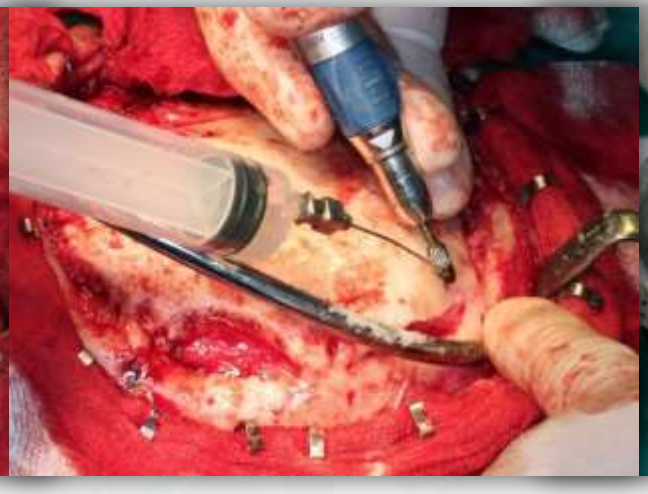
CASE STUDY 1 – Cranial implant

Before the surgery

CASE STUDY 1 – Cranial implant

Surgery





CASE STUDY 1 – Cranial implant

Surgery

CASE STUDY 1 – Cranial implant

After the surgery – 2 weeks

CASE STUDY 1 – Cranial implant

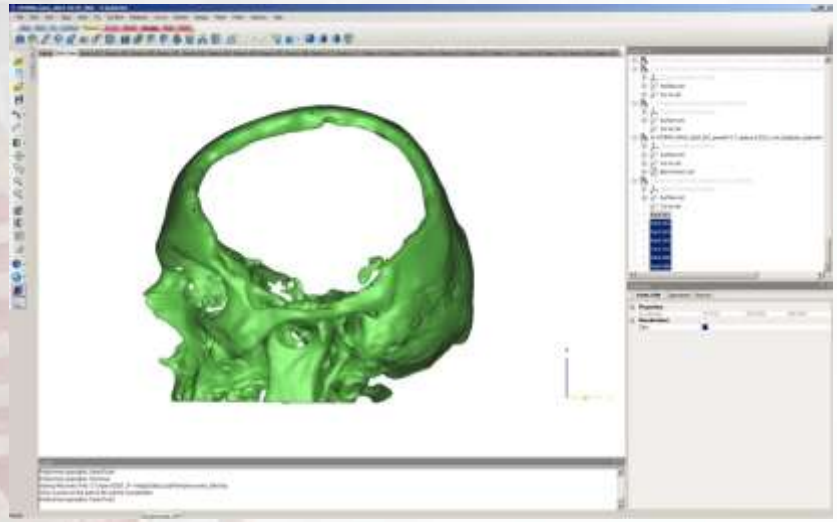
After the surgery –14 months

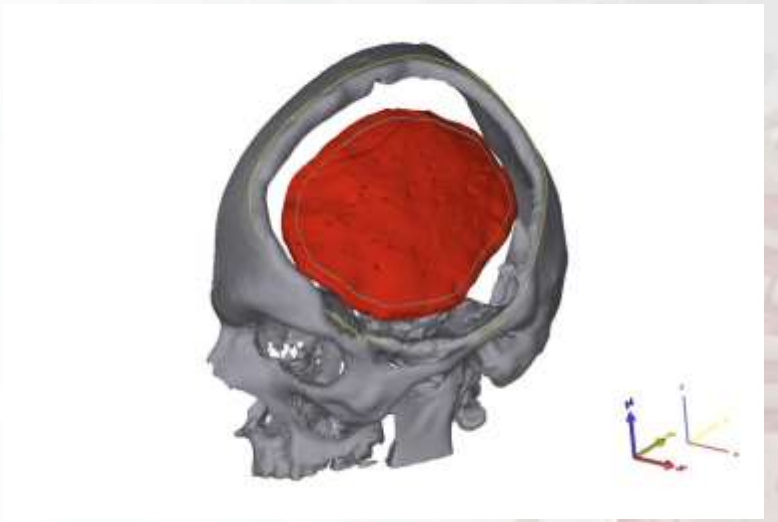
CASE STUDY 2 – Cranial implant

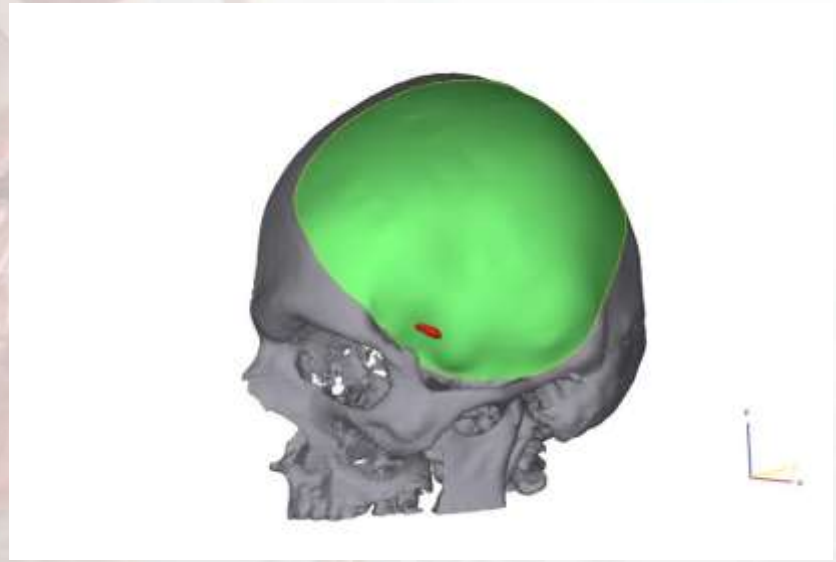
Patient data

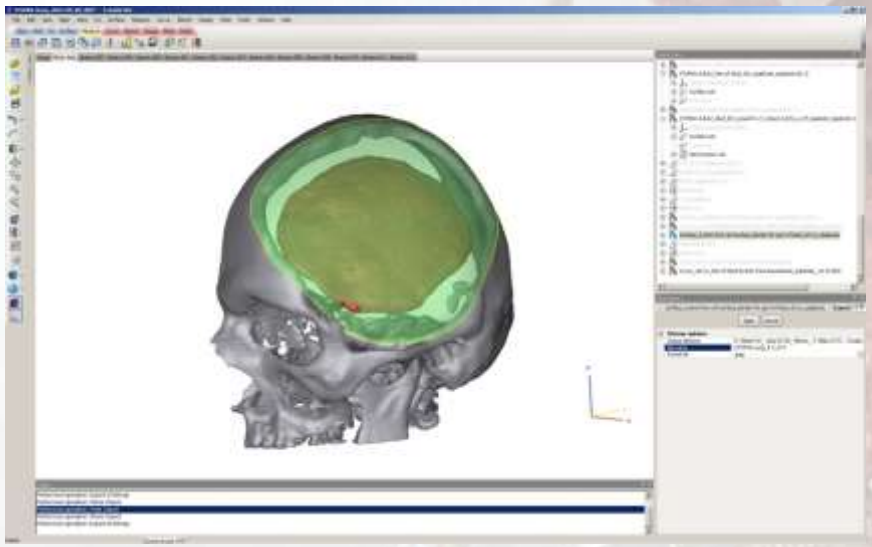
Age: 30
Cause of the injury: fall from the building (9 year ago)
In coma after the accident
Difficulty to walk and speak
Large cranial deffect: 33,8%

CASE STUDY 2 – Cranial implant
CAD/CAM modeling

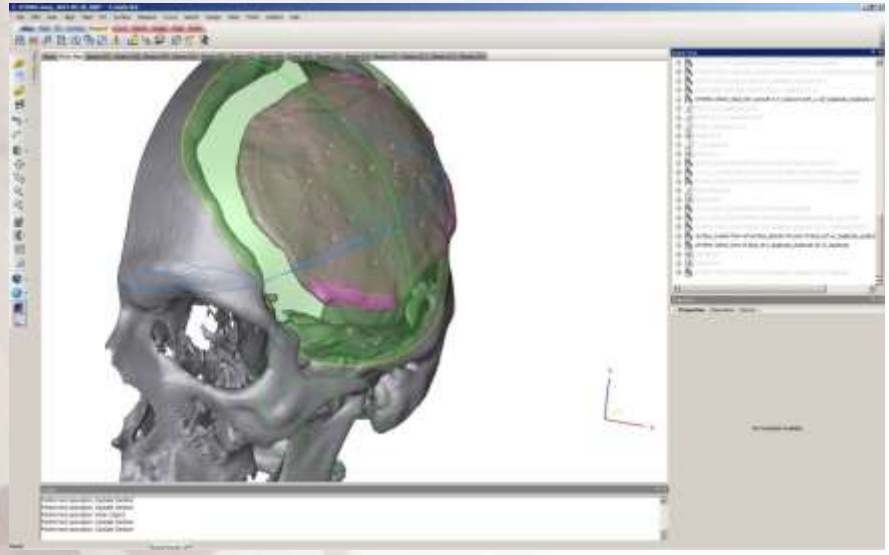


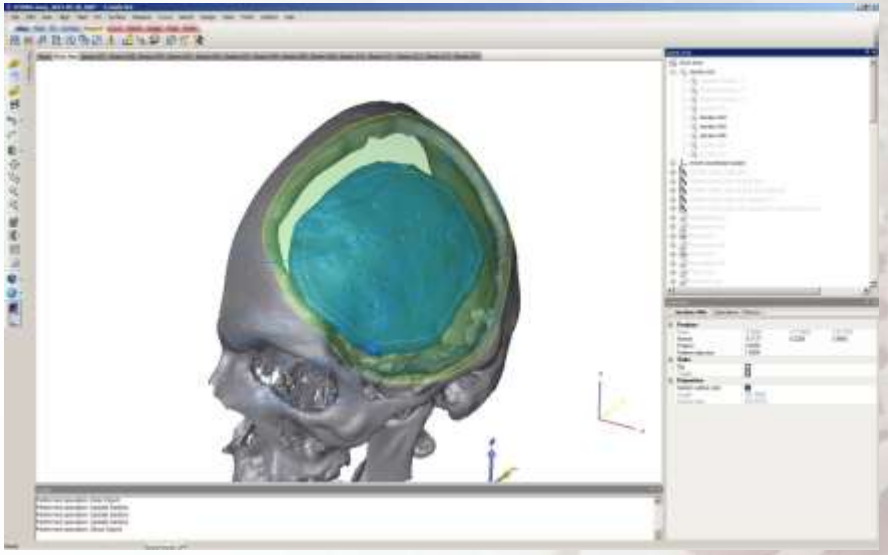


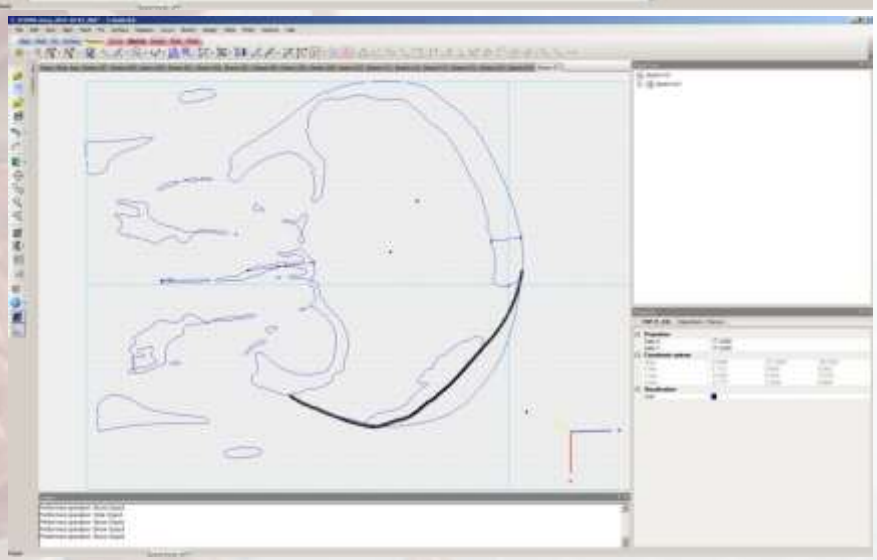


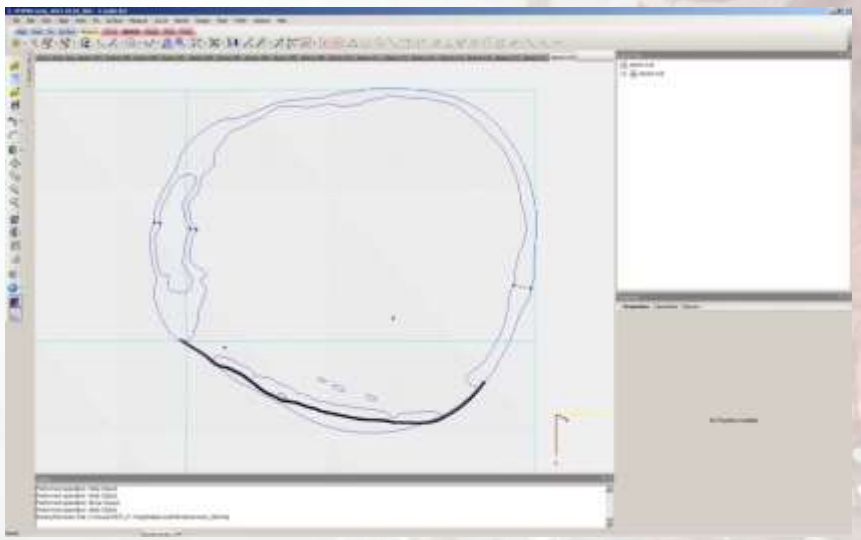


CASE STUDY 2 – Cranial implant
CAD/CAM modeling

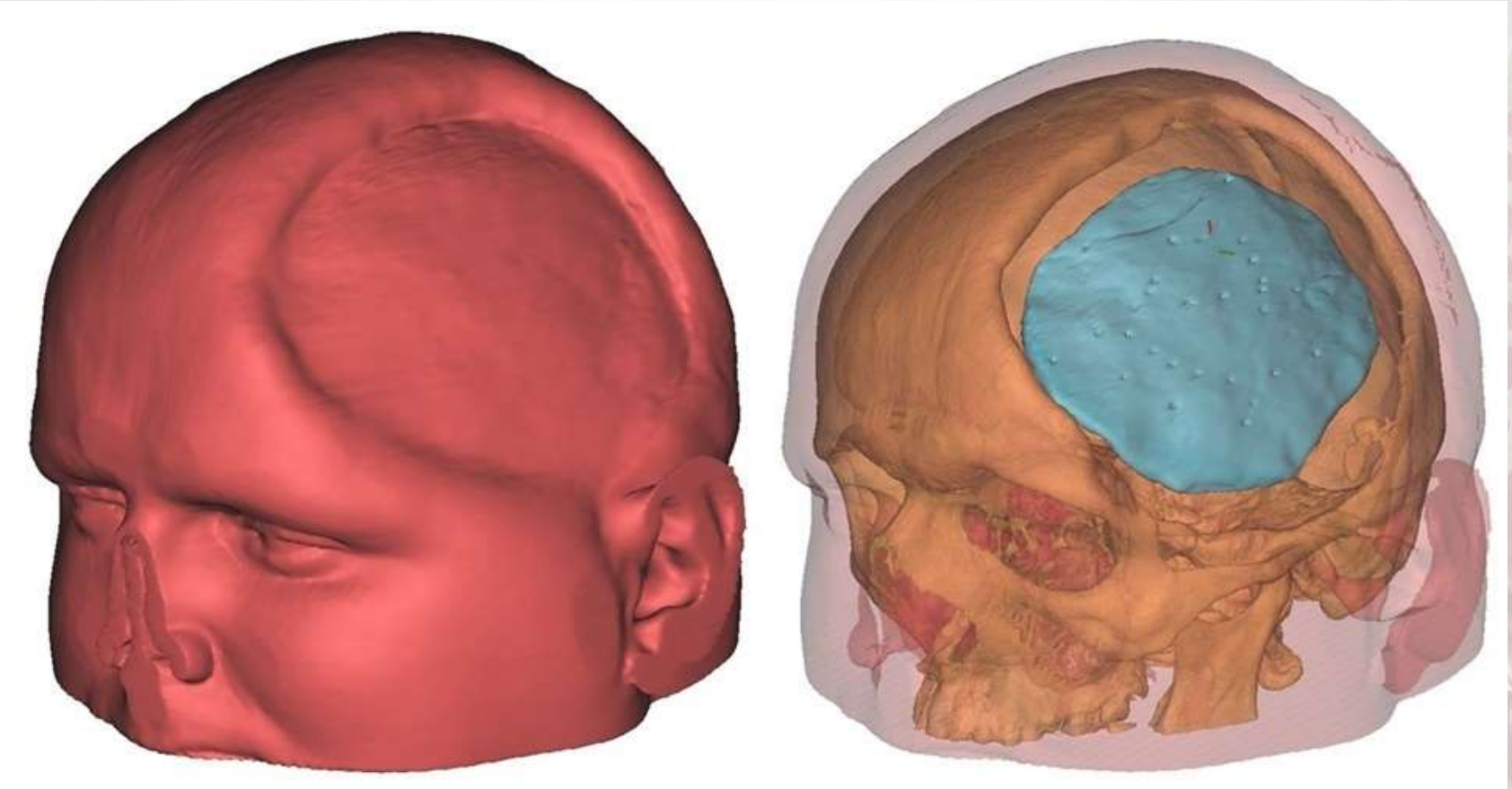




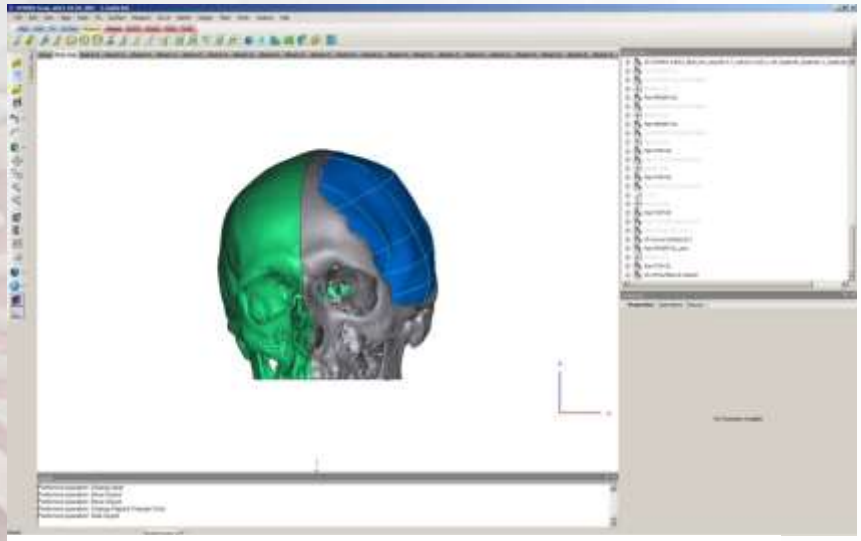


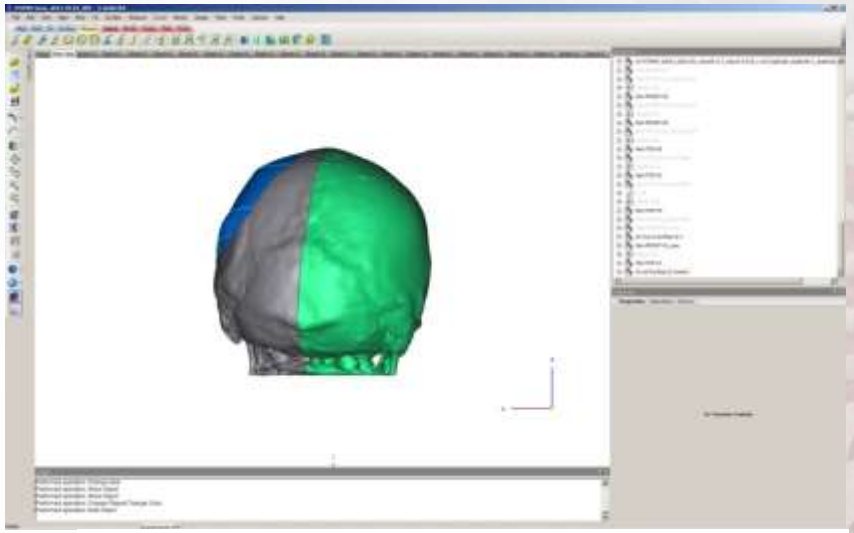


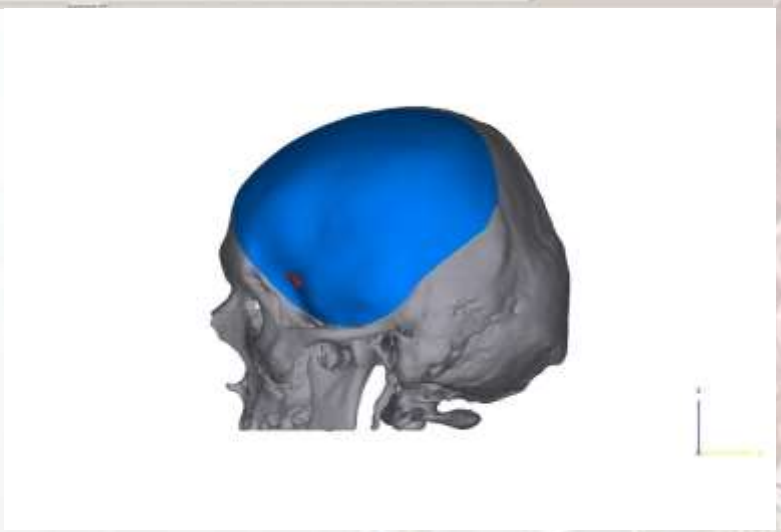
CASE STUDY 2 – Cranial implant
CAD/CAM modeling



CASE STUDY 2 – Cranial implant
CAD/CAM modeling

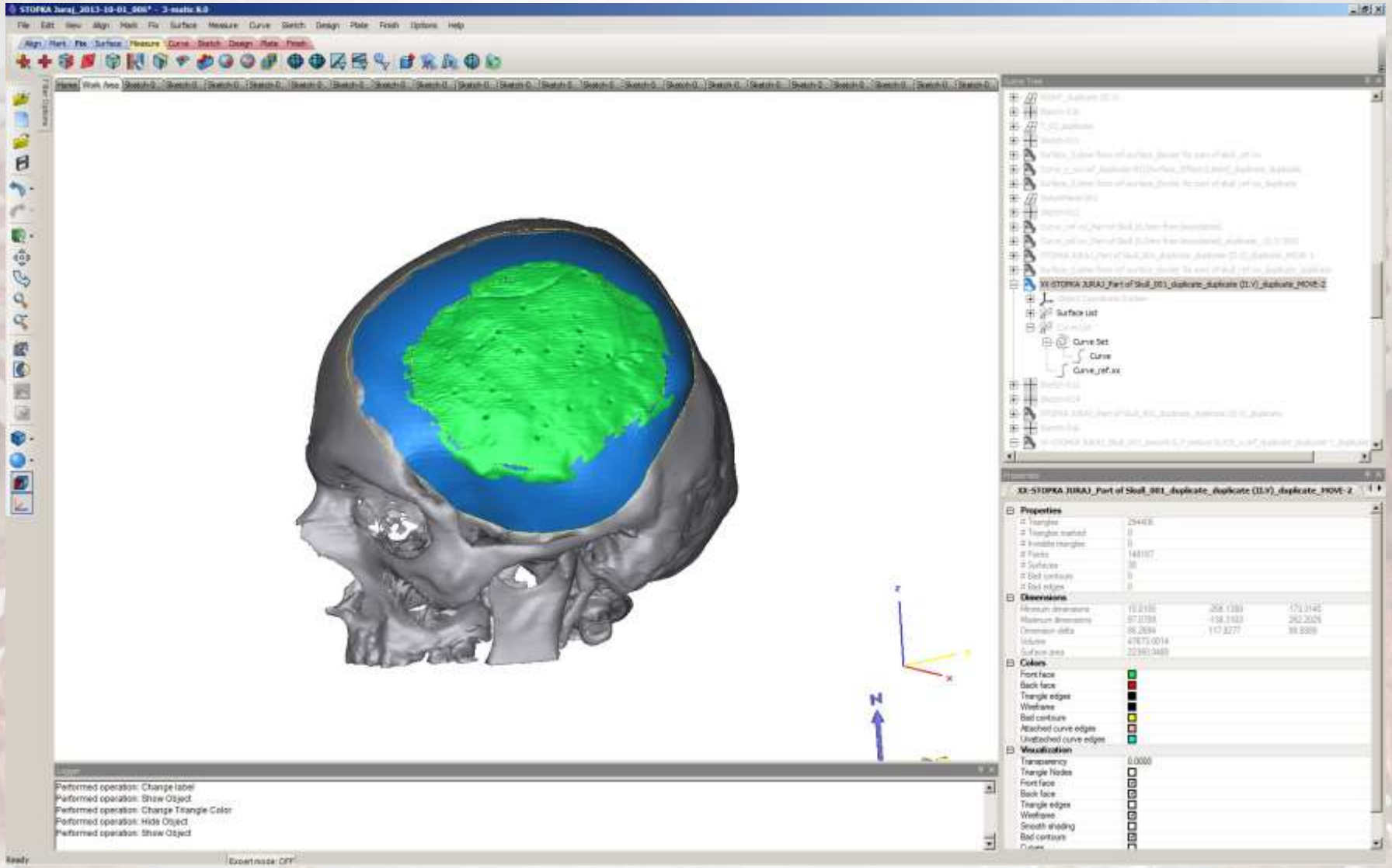






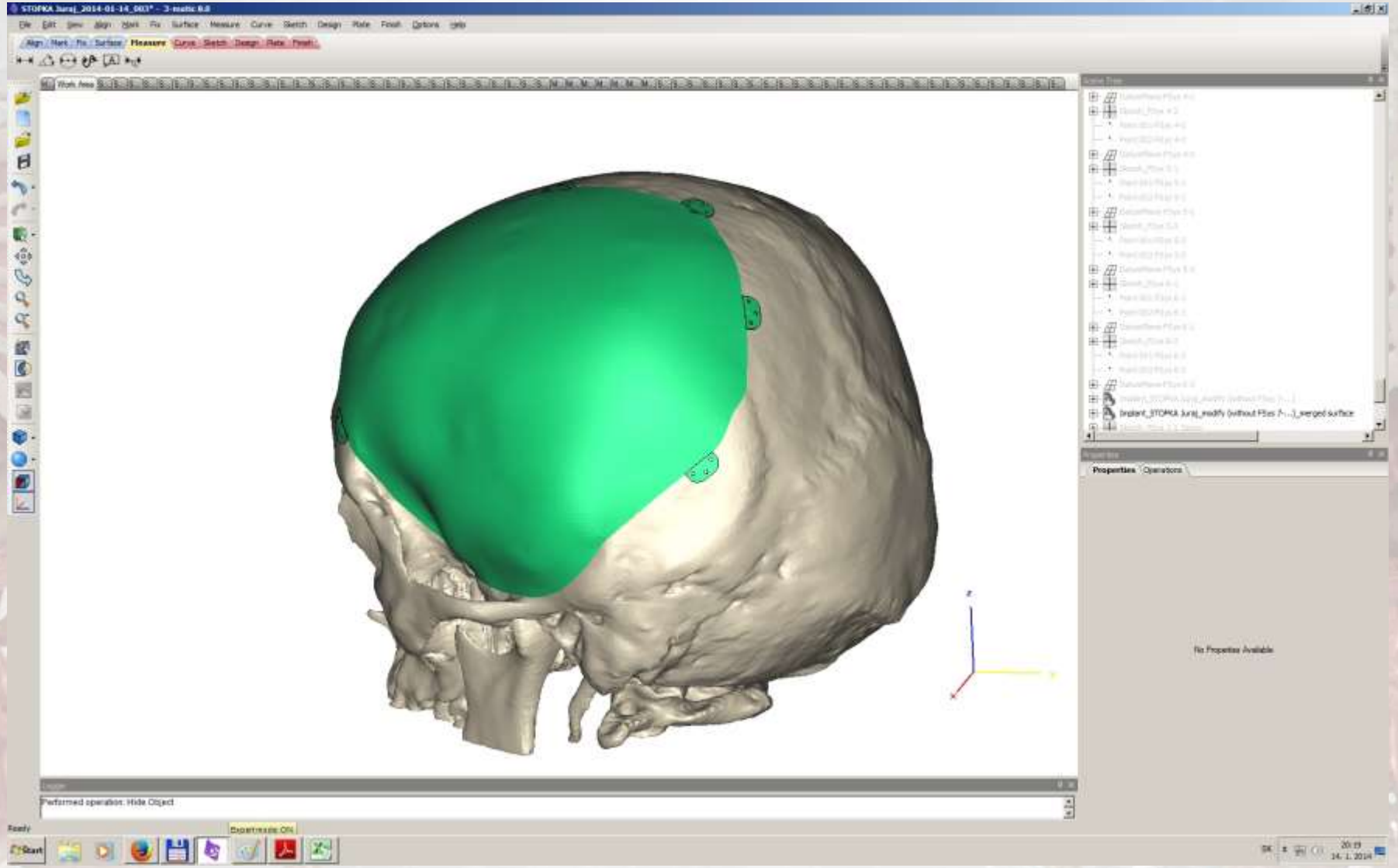
CASE STUDY 2 – Cranial implant

CAD/CAM modeling – Variant 1



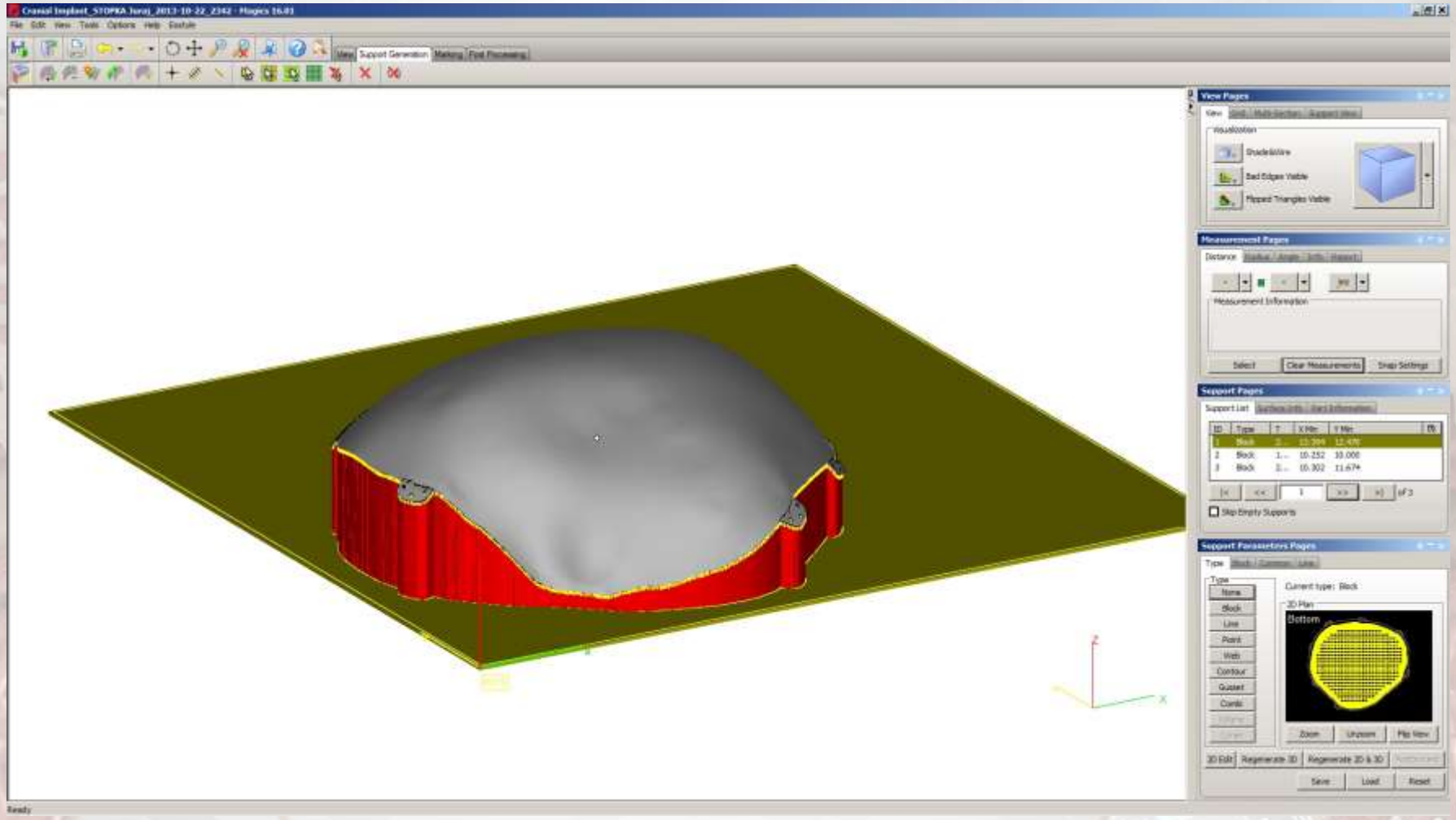
CASE STUDY 2 – Cranial implant

CAD/CAM modeling – Variant 2



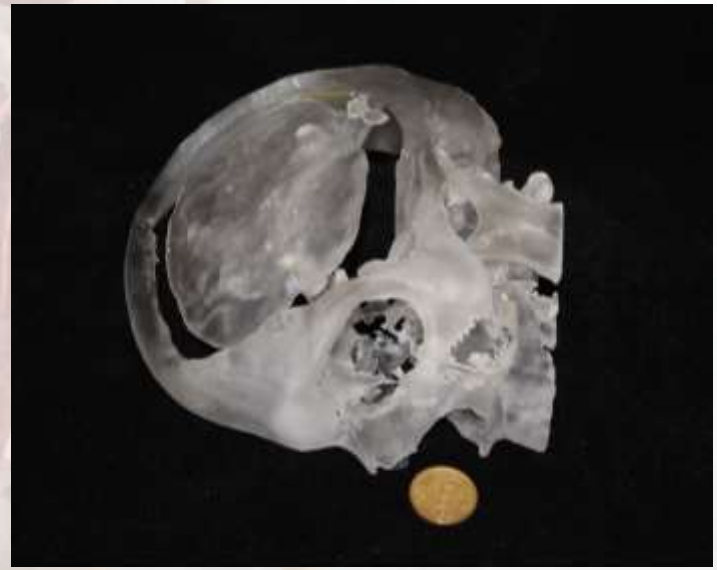
CASE STUDY 2 – Cranial implant

CAD/CAM modeling – Support design



CASE STUDY 2 – Cranial implant

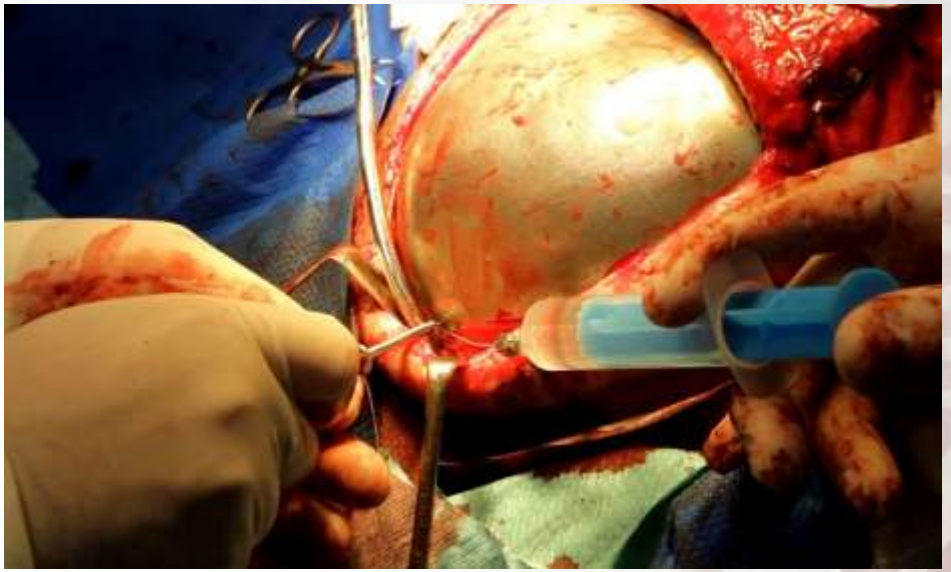
Plastic referential models and final product



Material: Ti-6Al-4V (Grade 5) titanium alloy
Weight: 125 g
Size: 120 cm^2
Technology: DMLS
Fixation: 21 screws, ϕ 1,2 mm

CASE STUDY 2 – Cranial implant

Surgery



CASE STUDY 2 – Cranial implant

Surgery - video

CASE STUDY 2 – Cranial implant

Before and after the surgery

CASE STUDY 2 – Cranial implant

Before and after the surgery

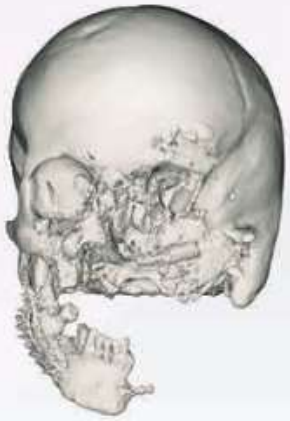
CASE STUDY 3 – Maxillofacial implant

Patient data

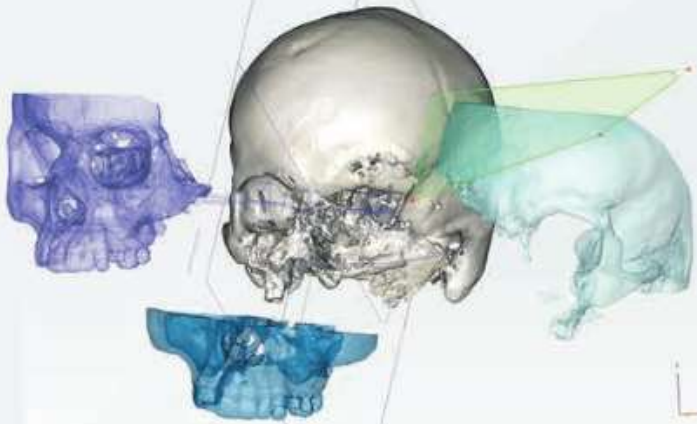
Age: 34
Cause of the injury: car accident
Large deffect: 85,84 % of the face

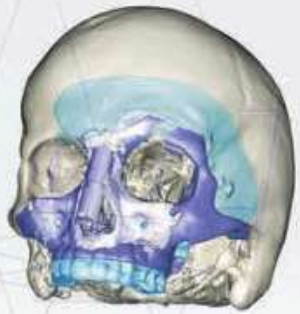
CASE STUDY 3 – Maxillofacial implant

CAD/CAM modeling



01/ a patient with an extensive defect in the facial and maxillofacial area

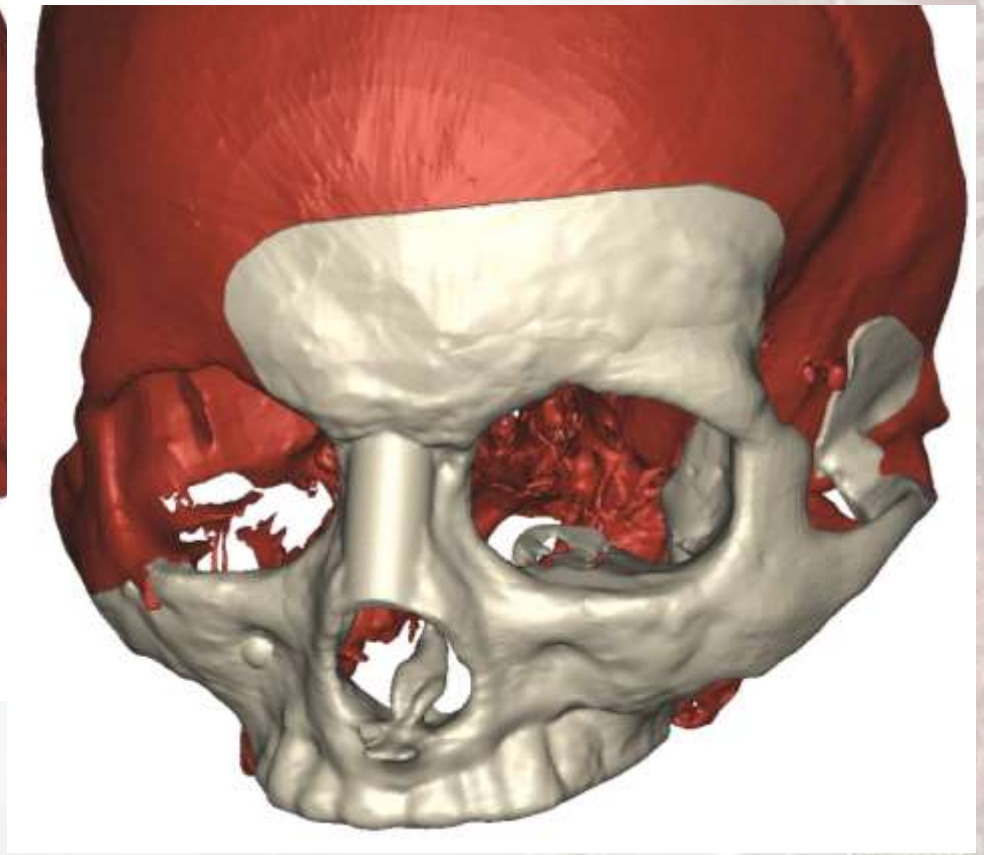




02/ 4 various sources of anatomical data were used for the restoration

CASE STUDY 3 – Maxillofacial implant

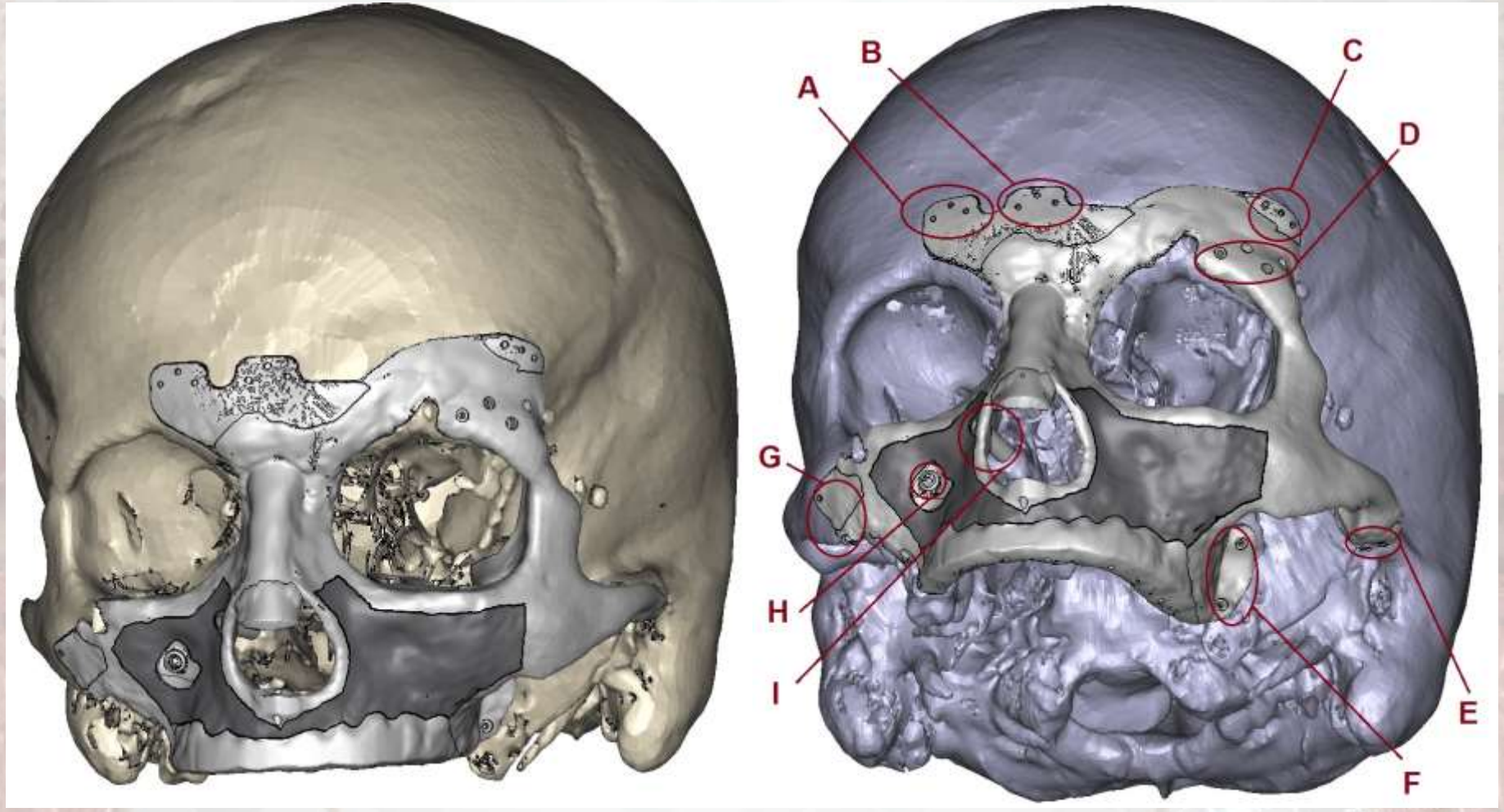
CAD/CAM modeling – variant 1



Weight: 260 g

CASE STUDY 3 – Maxillofacial implant

CAD/CAM modeling – variant 2



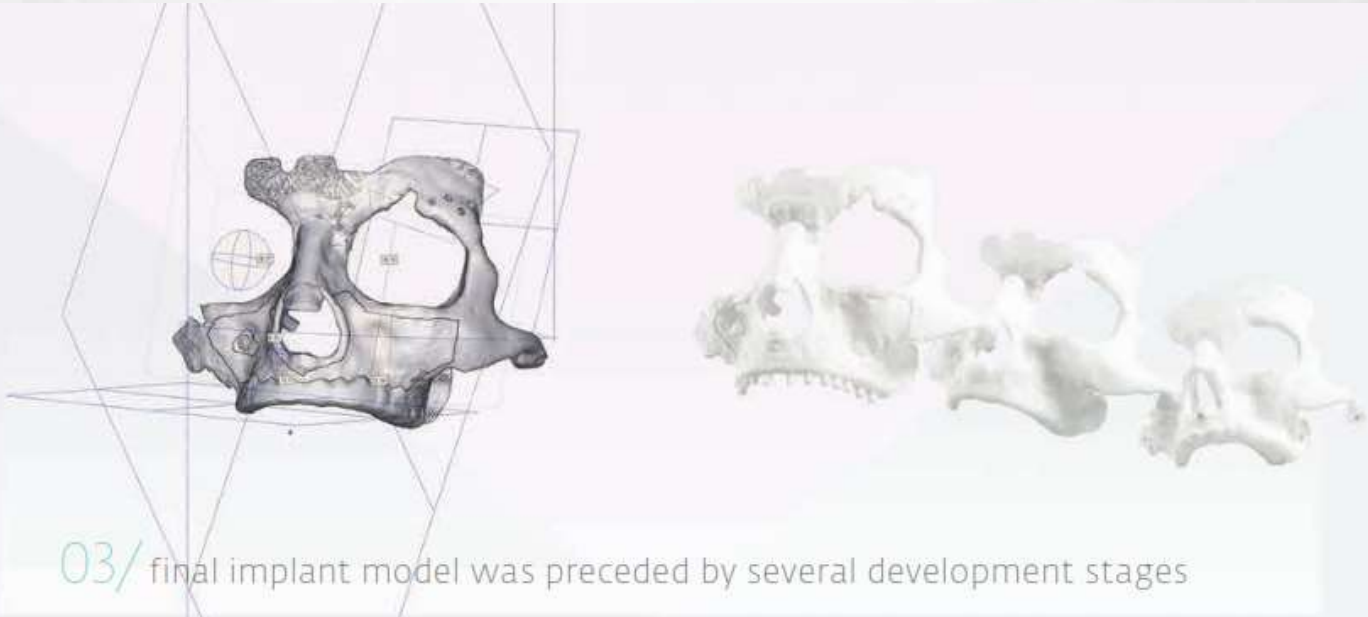
Weight: 173 g

CASE STUDY 3 – Maxillofacial implant

Plastic referential models (variants)

CASE STUDY 3 – Maxillofacial implant

Final implant and patient after the surgery

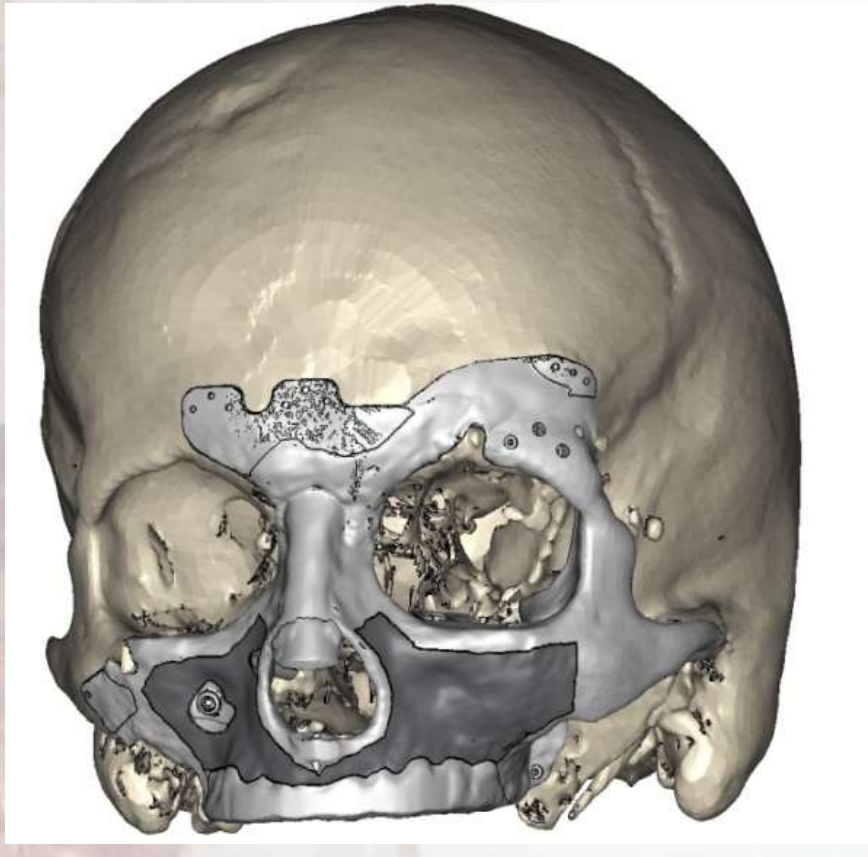


03/ final implant model was preceded by several development stages

04/ the patient is currently after the most demanding surgery,
3 subsequent interventions are planned to complete the restoration

CASE STUDY 3 – Maxillofacial implant

Final implant



CASE STUDY 3 – Maxillofacial implant

Final implant

CASE STUDY 3 – Maxillofacial implant

Surgery

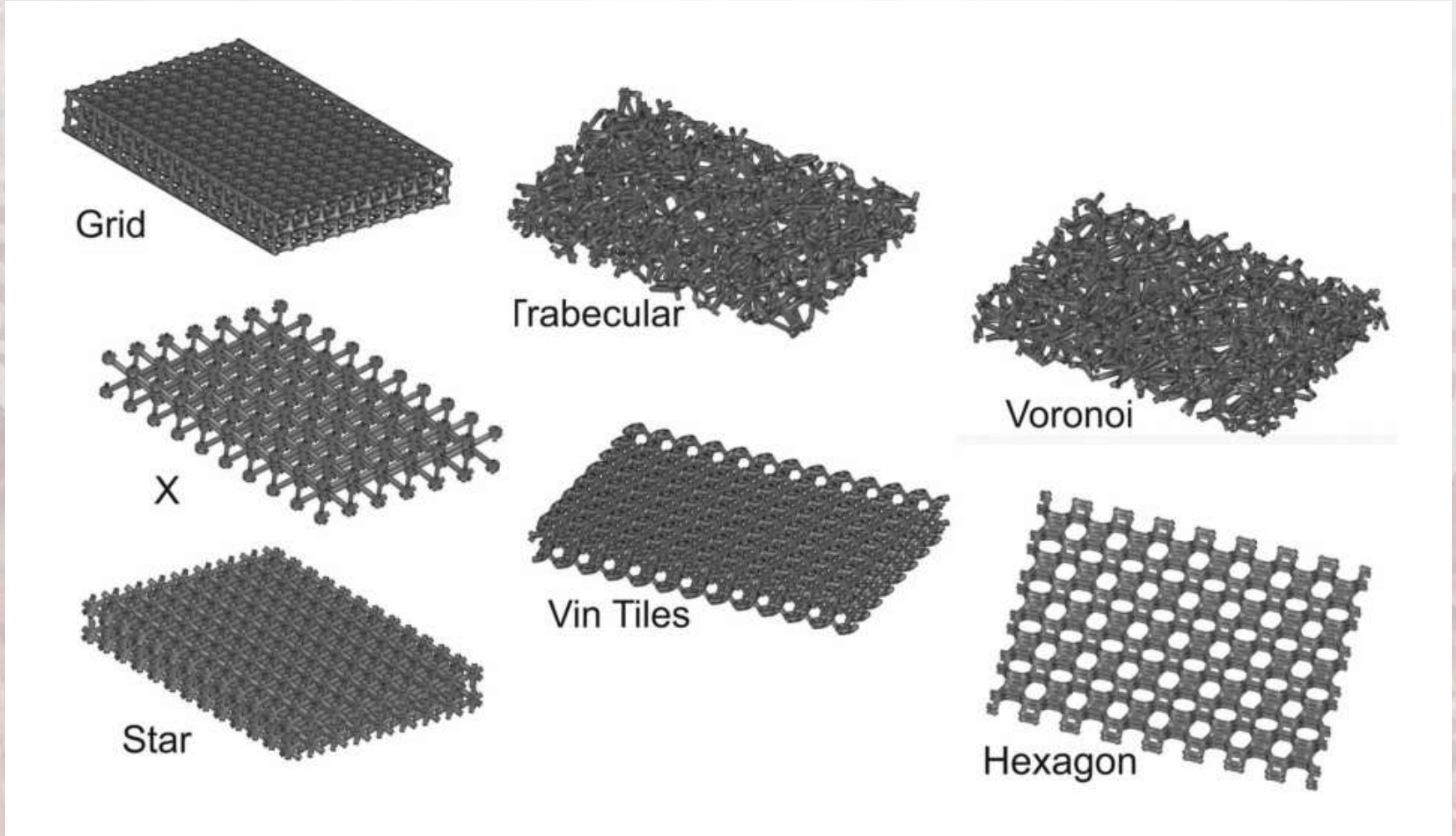
AM OF POROUS STRUCTURES

AM facilitates the manufacture of implants with the porous structure that enables us to create implants with physical properties very similar to human bone properties

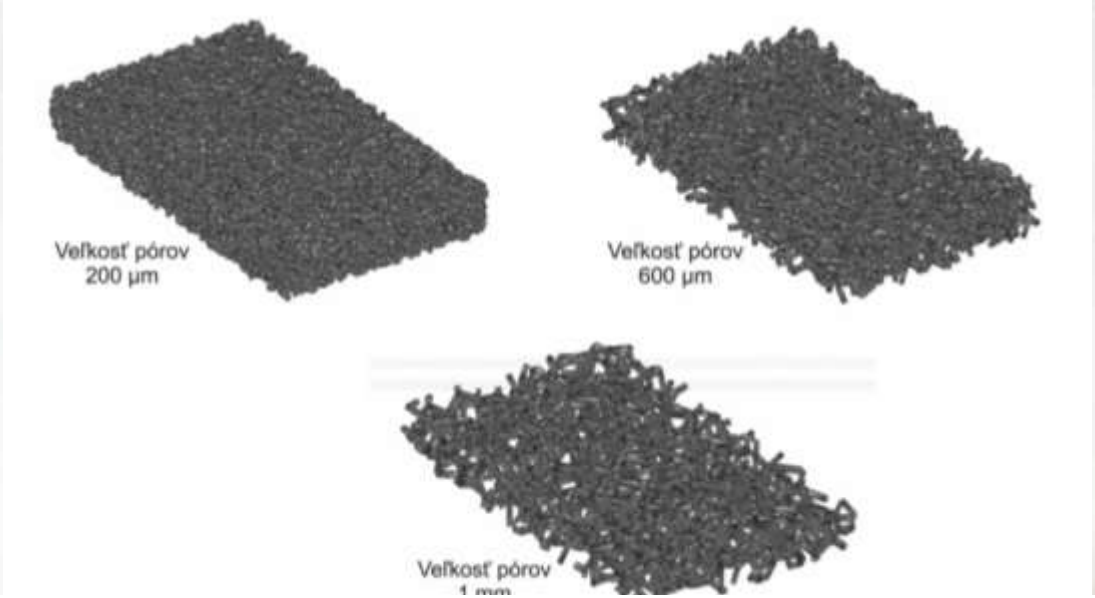
this unique structure improves the osteointegration and reduces the implant weight

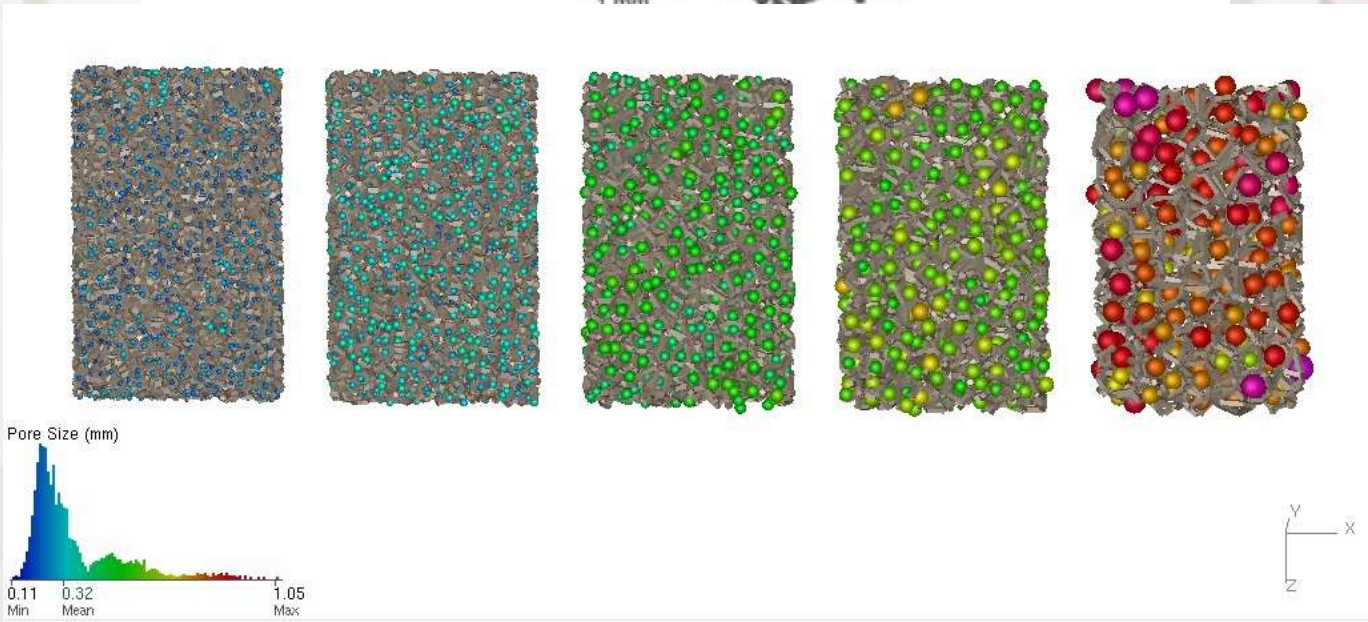
porous structure is manufactured with various geometric shapes and pore sizes

AM OF POROUS STRUCTURES

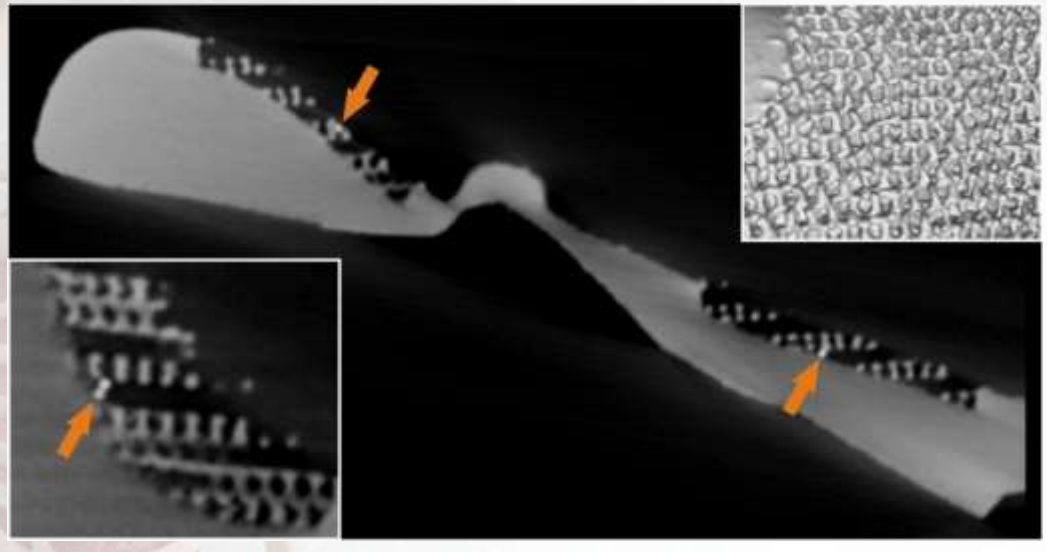


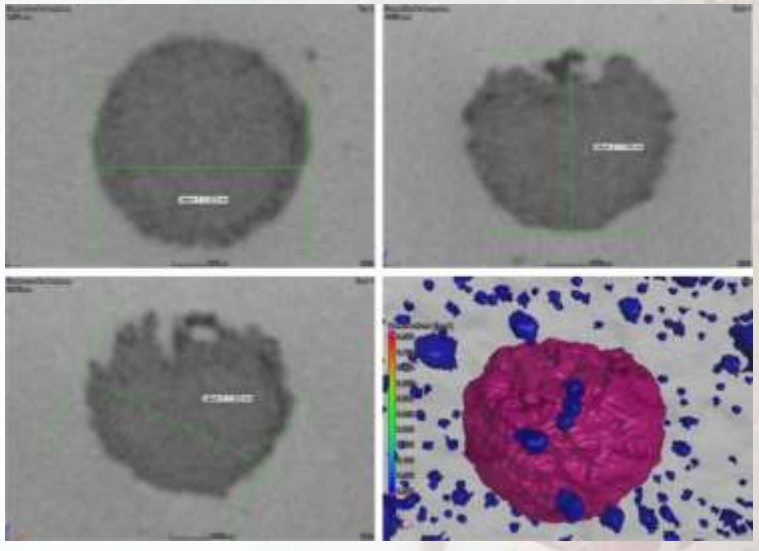
AM OF POROUS STRUCTURES

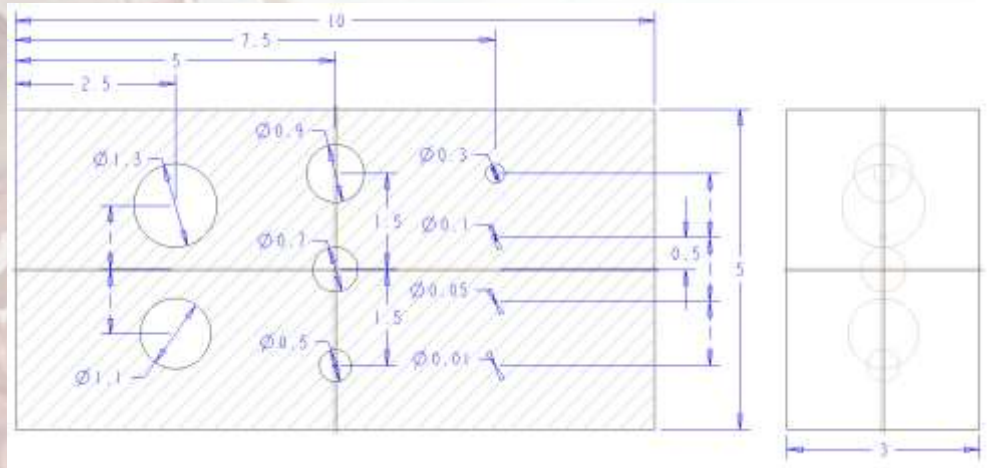


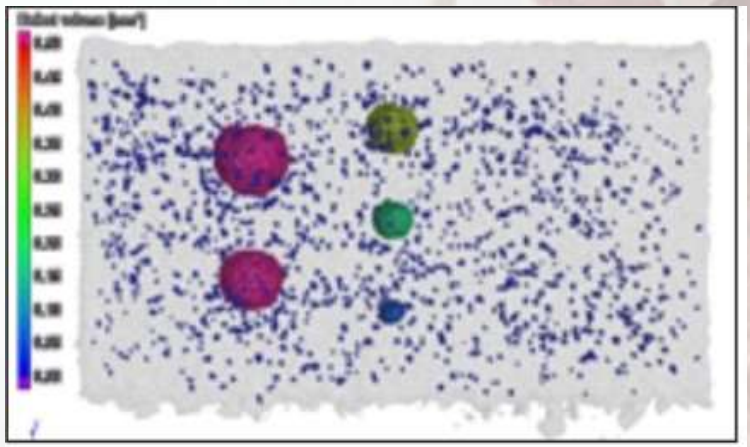


AM OF POROUS STRUCTURES



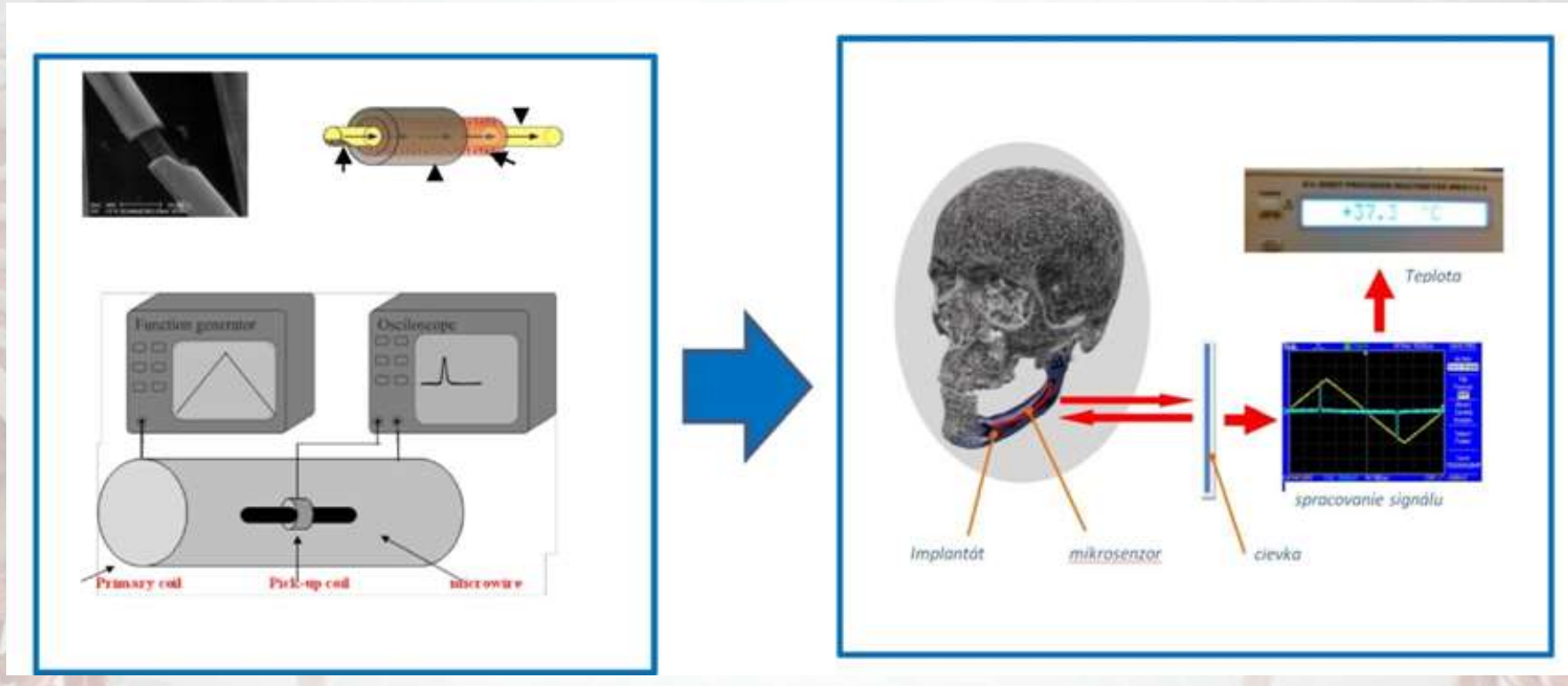






60 mm

R&D ACTIVITIES



PARTNERS


eos
e-Manufacturing Solutions


ProSpon


ZEISS


WITHIN


BEZNOSKA


Materialise
innovators you can count on


enbicore

CEIT biomedical engineering

Thank You for Your attention